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#### 1 DEFINITIONS, ABBREVIATIONS AND ACRONYMS

When used in this Management System Guideline ("MSG"), the following terms have the meanings set forth below:

**ANTI-CORRUPTION LAWS**: the Italian Criminal Code, the Legislative Decree 231 and other applicable provisions, the FCPA, the UK Bribery Act, other public and commercial anti-bribery laws in effect around the world, and international anti-corruption treaties such as the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions, and the United Nations Convention against Corruption.

#### AT-RISK PERSONNEL: any Esaote employee or manager, who:

- (a) is likely to have Relevant Contact with a Public Official, in connection with his/her work;
- (b) supervises employees or Business Partners likely to have such Relevant Contact; or
- (c) is able to enter into contracts with third parties on Esaote's behalf or have any significant influence over the decision making in relation to the awarding of those contracts; or
- (d) is involved with internal controls issues or other activities covered by the Anti-Corruption Laws; and
- (e) any Esaote's employee identified as at-risk by a manager in one of the above categories.

**BUSINESS PARTNER**: any non-employee party receiving and/or providing products or services from/for

Esaote or from/for Esaote's Business Partners, (i) which acts on behalf of Esaote, or (ii) is likely to have Relevant Contact with a Public Official in the course of its work for or on behalf of Esaote (i.e., Intermediaries, Consultants, distributors, dealers, agents, franchisees, Joint Ventures, etc.).

**CODE OF CONDUCT**: Esaote's Code of Conduct.

**CONSULTANT**: an independent individual or a company working on Esaote's behalf with the aim of providing intellectual expert advice or services, used by Esaote to support management decisions.

**CONTRACT HOLDER**: person responsible for the correct execution of the contract and for the technical, operational and financial control of goods, works and services. He is the reference person for the contracts for which he has been appointed, both within Esaote and towards third parties. The Contract Holder role is accepted by virtue of the Contract Holder's organizational position.

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**ESAOTE**: Esaote S.p.A. and its Subsidiaries.

**ESAOTE ANTI-CORRUPTION REGULATIONS**: Esaote MSG and Esaote Procedures finalized to prevent bribery-related risks.

It is responsibility of each single process owner of the relevant MSG to update the regulations (or to issue new regulations) concerning the subjects listed above, also to ensure compliance with this MSG. In defining such regulations, the Esaote Compliance Officer must be consulted.

**ESAOTE PERSONNEL**: the directors, officers, members of corporate bodies, managers and employees of Esaote.

**FACILITATION PAYMENTS**: unofficial payments made to a Public Official in order to expedite, to facilitate or to secure the performance of routine governmental action or necessary action by the Public Official. They are sometimes referred to as "speed" or "grease" payments.

**FAMILY MEMBER**: the Public Official's spouse; the Public Official's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; the spouse of any of these people; and any other individuals who share the same household; and the private party's spouse; the private party's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; the spouse of any of these people; and any other individuals who share the same household.

FCPA: U.S. Foreign Corrupt Practices Act 1977, as amended from time to time.

**INTERMEDIARY**: an independent individual or a company that Esaote proposes to retain to: (i) promote the commercial interests of Esaote and/or any of its Subsidiaries in relation to a single transaction/project; (ii) facilitate the stipulation and/or execution of contracts with third parties; and/or (iii) put in contact/introduce Esaote S.p.A. and/or any of its Subsidiaries to one or more other parties for the purpose of bringing/generating or retaining a business.

**JOINT VENTURES**: contracts aimed at establishing joint ventures, consortia, temporary associations of companies (ATI), associations, cooperation agreements or other entities with or without legal status, in which Esaote holds an interest.

**LEGISLATIVE DECREE 231**: Italian Legislative Decree June 8, 2001, No. 231, as amended from time to time.

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**MODEL 231**: the Model concerning the organization, management and controlling activities of Esaote (ex Legislative Decree 231 of 2001) approved by the Board of Directors of Esaote S.p.A. on 1.2.2012.

**PROCEDURES**: Esaote's procedures aimed at preventing bribery-related risks, including Esaote Procedure on:

- (a) Third Parties;
- (b) Standard contractual clauses to apply with Business Partners;
- (c) Gifts, Travel, Hospitality and Expenses of third parties;
- (d) Joint Venture agreements;
- (e) Sponsorship agreements and Donations;
- (f) Ordinary reporting and confidential reporting ("whistleblowing").

#### **PUBLIC OFFICIAL:**

- (a) anyone who performs public functions in a legislative, judicial or administrative capacity;
- (b) anyone acting in an official capacity for or on behalf of (i) a national, regional or local government, (ii) an agency, department or instrumentality of the European Union or of an Italian or a non-Italian national, regional or local government, (iii) an Italian or a non-Italian government-owned or government-controlled or government-participated company, (iv) a public international organization such as the European Bank for Reconstruction and Development, the International Bank for Reconstruction and Development, the International Monetary Fund, the World Bank, the United Nations or the World Trade Organization, or (v) an Italian or a non-Italian political party, member of a political party, official or candidate for political office;
- (c) anyone in charge of providing a public service, i.e. whoever performs a public service for whatever reason, where public service means an activity that is governed in the same way as a public function, except that the power vested in the latter is absent. The performance of basic ordinary tasks and exclusively manual work is excluded.

#### **RELEVANT CONTACT**: any direct or indirect contact related to:

- (a) influencing any legislative, executive, administrative, judicial or other public policy body or personnel or any political party or public international organization;
- (b) any governmental inquiry, inspection, audit, assessment, licensing, permitting, registration or similar administrative, regulatory or enforcement action;
- (c) any potential or actual government contract or other transaction or business involving a
  governmental body or corporation owned or controlled by a government, a political party or a
  public international organization;

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- (d) entertainment, training, reimbursement of expenses or gifts for a Public Official;
- (e) any other negotiation, settlement or consultation with a government body or public international organization or Public Official, other than consultation that does not involve advocating any position if such consultation is with a Public Official acting in a ministerial, administrative or legal capacity and solely for the purpose of seeking an interpretation or advisory opinion regarding application of regulations, explanation of procedures for filing documents with the government, or legal aspects of a private transaction; and
- (f) similar activities.

**SUBSIDIARY**: any entity that is directly or indirectly controlled by Esaote S.p.A.(1) in Italy and abroad.

**SUBSIDIARIES ANTI-CORRUPTION REGULATIONS**: the guidelines, procedures and/or operating instructions adopted by the Subsidiaries pursuant to Section 3.3 of this MSG, as defined therein.

**SUPPLIER**: independent entity (individual, legal person or joint ventures) which provides goods or services to another entity under terms specified in a contract.

**UK BRIBERY ACT**: the United Kingdom Bribery Act 2010 (and all associated secondary legislation), as amended from time to time.

#### 2 ROLES AND RESPONSIBILITIES

**COMPLIANCE OFFICER:** a resource within the Company entrusted with the management and implementation of policies aimed at avoiding or reducing the exposure to liability for any violation of national or international regulations, decisions of competent authorities or other applicable rules of conduct. The Compliance Officer: (i) ensures knowledge of applicable regulations; (ii) makes proposals, preparation and update of compliance policies for preventing any corporate conduct that may be contrary to regulations; (iii) acts as reference person for Group companies; (iii) reports on the implementation and monitoring of compliance policies to the Board of Directors; (iv) assists the 231 Supervisory Body in relation to any Legislative Decree 231 issue; and (v) carries out communication and training on compliance policies.

(1) The list of these companies is that included in the appendix "Controlled subsidiaries" of the most recent approved consolidated financial statement.

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**INTERNAL AUDIT:** if appointed, a professional or a company appointed by Esaote S.p.A. responsible for the examination and independent evaluation of the internal control system, in order to verify the compliance with the requirements of this MSG, on the basis of its periodical audit plan approved by the Board of Directors of Esaote S.p.A. based on the preliminary opinion of the Compliance and Audit Committee.

**HUMAN RESOURCES DEPARTMENT:** the human resources department of Esaote S.p.A., responsible for the activities provided under Section 18.

**231 SUPERVISORY BODY:** the supervisory body (*Organismo di Vigilanza*) of Esaote S.p.A., as defined in Esaote Organizational Model and appointed pursuant to the Legislative Decree 231.

#### 3 INTRODUCTION

#### 3.1 Scope

One of the key purposes for Esaote's reputation is to maintain the ability to conduct business with loyalty, fairness, transparency, honesty, integrity and respect for, and compliance with, the laws, regulations, similar mandatory requirements and international standards and guidelines, both domestic and foreign, that apply to its business.

This MSG is being adopted for the purpose of providing a systematic framework to the anticorruption related regulations that Esaote is designing and implementing.

This MSG is designed to optimize Esaote's compliance with its Model 231 and with Anti-Corruption Laws that make it unlawful for companies, their subsidiaries and their employees or business partners to pay or accept, directly or indirectly, bribes, kickbacks or other improper payments for the purpose of obtaining or retaining business or securing an unfair business advantage.

This MSG is inspired by the behaviour principles described in the Code of Conduct and is designed to provide to the Esaote Personnel and to all those who work, in Italy and abroad, for or on behalf of Esaote, the principles and rules to be met in order to ensure compliance with Anti-Corruption Laws.

For the definition of capitalized words, see Section 1 – Definitions, abbreviations and acronyms.

#### 3.2 Application

This MSG has been approved by the Board of Directors of Esaote S.p.A.; its adoption and enforcement is mandatory for Esaote S.p.A. and all its Subsidiaries.

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Esaote will also use its influence, to the extent reasonable under the circumstances, to cause companies and entities in which Esaote has a non-controlling interest and Business Partners to meet the standards set out in this MSG by adopting and maintaining an adequate internal control system which is consistent with the requirements established by the Anti-Corruption Laws. In any case, the representatives indicated by Esaote in such companies and entities shall use their best efforts to cause the standards set out in this MSG to be adopted. The circumstances which are significant for the adoption of these standards include the degree of Esaote's ownership or interest in the company or entity (i.e. Joint Venture, consortium) and the laws and regulations governing the business operations in the country in which the company or entity is located or the activities are based.

#### 3.3 Implementation modalities: Subsidiaries

Each Subsidiary shall adopt this MSG by a board of directors' resolution (or the corresponding body/structure/role, when the governance of the Subsidiary does not provide such board) promptly. The same board of each Subsidiary shall resolve to adopt and implement:

- (a) Esaote Anti-Corruption Regulations; and
- (b) additional internal regulations, if needed, to address specific risks or the way the company conducts business or to comply with applicable local laws and/or to address features of the company's specific situation (the internal regulations indicated sub (b) being referred to herein as the "Subsidiaries Anti-Corruption Regulations").

#### 4 REFERENCE

#### 4.1 The Anti-Corruption Laws

Almost all countries have laws prohibiting corruption of their own government officials, and many countries have laws criminalizing corruption of other countries' officials. The United States, Italy and many other countries also have laws that prohibit commercial bribery among private parties.

Because Esaote is headquartered in Italy, Esaote and Esaote Personnel are subject to Italian law and, in particular, to the provisions of Legislative Decree 231. As Esaote is a multinational organization, doing business in several countries and jurisdictions around the world, Esaote and Esaote Personnel are also subject to the laws of many other countries, including those laws ratifying international conventions, prohibiting corruption of Public Officials and private parties, such as:

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- (a) OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions;
- (b) United Nations Convention Against Corruption;
- (c) Foreign Corrupt Practices Act (FCPA) issued in the United States;
- (d) UK Bribery Act issued in the United Kingdom,

all of them as amended from time to time.

In order to comply with both the Legislative Decree 231 and UK Bribery Act, Esaote has introduced in this MSG the prohibition of the corruption among private parties, other than Public Officials.

#### Anti-Corruption Laws:

- (a) prohibit both direct and indirect payments including payments to anyone while knowing the payment will be shared with a Public Official or private party as well as offers or promises to pay or give anything of value, or other advantages to a Public Official or to a private party for a corrupt purpose. Under the Anti-Corruption Laws, Esaote and/or Esaote Personnel can be held responsible for a corrupt offer or payment made by anyone acting on behalf of the company in connection with Esaote business and when Esaote and/or Esaote Personnel knew or reasonably should have known this offer or payment was improper; and
- (b) require companies to make and keep books, records and accounts which, in reasonable detail, accurately and fairly reflect their transactions, expenses (even if not "material" in an accounting sense) and acquisitions and disposals of their assets(2).

Even inaccuracies in the reporting of non-corrupt payments constitute violations. False records may trigger tax and other legal liabilities.

#### 4.2 Consequences of non-compliance with anti-corruption provisions

In recent years, enforcement of Anti-Corruption Laws has become more intensive and the penalties significantly more severe. The adverse consequences for individuals and corporations who violate Anti-Corruption Laws include economic sanctions (fines, in some cases unlimited), while individuals may be sentenced to prison terms or suffer other penalties. Other legal consequences may derive

(2) Government enforcement agencies are particularly concerned with accounting books and records that:
(i) fail to record transactions at all; (ii) have been falsified to disguise aspects of transactions otherwise correctly recorded; or (iii) correctly set forth the quantitative aspects of transactions but fail to record the qualitative aspects that would have revealed the transactions' illegality or impropriety. However, the recordkeeping provisions are broader in application than the area of these concerns.

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from such violations including debarment from contracting with public entities, confiscation/disgorgement of money made or damages claims. Even more importantly, such events cause a material adverse effect on a company's reputation.

Note also that, in order to maximize the effectiveness of the penalties, companies are usually prevented from indemnifying their personnel against liability under Anti-Corruption Laws.

#### 4.3 Support

Contents of applicable laws and Anti-Corruption Laws may change at any time, so it is important to obtain up-to-date legal advice before making any commitment on behalf of Esaote. To this purpose:

- (a) questions with respect to the content of Anti-Corruption Laws, the Code of Conduct, or any of the matters discussed in this MSG, or their application to specific situations, and/or
- (b) questions with respect to internal controls provisions of the Anti-Corruption Laws, or any of the matters discussed in this MSG, or their application to specific situations

must be directed to the Compliance Officer of Esaote S.p.A.

#### 5 STATEMENT OF POLICY

Esaote prohibits bribery without any exception. In particular, Esaote prohibits:

- (a) offering, promising, giving, paying or authorising anyone to give or pay, directly or indirectly, a financial or other advantage to a Public Official or private party (**Active Bribe**);
- (b) accepting the request from, or solicitation by, or authorising anyone to accept the request from, or solicitation by, directly or indirectly, a Public Official or private parties of a financial or other advantage (**Passive Bribe**);

when the intention is:

- (a) to induce a Public Official or private party to perform improperly any function of a public nature or any activity connected with a business or reward them for the improper performance of such a function or activity;
- (b) to influence any official act (or failure to act) by a Public Official or any decision in violation of any lawful duty;
- (c) to obtain, secure or retain business or an improper advantage in the conduct of business; or
- (d) in any case, to violate the applicable laws.

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The prohibited conduct includes financial or other advantage offered or received by Esaote Personnel (Direct Bribery) or by anyone acting on behalf of Esaote (Indirect Bribery) in connection with Esaote business.

This prohibition is not limited to cash payments, and includes corrupt:

- (a) gifts:
- (b) entertainment, meals and travel;
- (c) in-kind contributions, such as sponsorships;
- (d) business, employment or investment opportunities;
- (e) insider information that could be used to trade in regulated securities or commodities;
- (f) personal discounts or credits;
- (g) Facilitation Payments;
- (h) assistance to or support of family members; and
- (i) other unjustified benefits or advantages.

Esaote prohibits any forms of bribery, including but not limited to those described above, to any person. A person subject to this MSG will be deemed to "know" that the payment or other advantage will benefit a Public Official or private party or his/her Family Members or designees if he/she has acted with conscious disregard or avoidance of warning signs or grounds for suspicion ("**Red Flags**") or with gross negligence, e.g., a failure to conduct the appropriate level of due diligence under the circumstances.

Compliance with Anti-Corruption Laws and this MSG is mandatory for all Esaote Personnel, At Risk Personnel, and Business Partners. Consequently:

- (i) all of Esaote's dealings with, or related to, or involving a Public Official must be conducted in compliance with this MSG and all related Esaote Anti-Corruption Regulations;
- (ii) all of Esaote's dealings with, or related to, private parties must be conducted in compliance with this MSG and all related Esaote Anti-Corruption Regulations;
- (iii) Esaote Personnel are responsible, each for their own area of competence, to be in compliance with the MSG and the Esaote Anti-Corruption Regulations. In particular, managers are responsible for supervising the compliance by their staff of the MSG and the Esaote Anti-Corruption Regulations and for taking steps to prevent, detect and report potential violations;
- (iv) no questionable or illegal practice (including Facilitation Payments) can ever be justified or tolerated because it is "customary" in the business or in the countries where Esaote operates.
   No performance goal should be imposed or accepted if it can be achieved only by compromising our ethical standards;

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- (v) Esaote Personnel who violate this MSG, the Esaote Anti-Corruption Regulations and/or Anti-Corruption Laws will be subject to discipline, up to and including termination and to any other legal actions to the extent necessary to protect Esaote's interests. Business Partners who violate this MSG and/or Anti-Corruption Laws will be subject to contractual remedies, including suspension of the execution and up to termination of the agreement, debarment from doing business with Esaote and damage claims;
- (vi) no Esaote Personnel will be subjected to demotion, penalty or any other adverse consequence for refusing to make a prohibited payment, even if such refusal results in a loss of business or other adverse consequence to the business.

#### 6 FACILITATION PAYMENTS

Facilitation Payments are expressly prohibited. It is not acceptable for any Esaote Personnel, or any of its Subsidiaries, or Business Partners, to make these sorts of payments in any circumstances.

#### 7 RELATIONSHIPS WITH HEALTHCARE PROFESSIONALS

Ethical relationships with healthcare professionals are critical to Esaote's mission of helping patients by developing and marketing new medical devices.

Appropriate marketing of medical devices ensures that patients have access to the services they need and that the mentioned devices are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals since they enable us to:

- (a) inform them about the benefits of our products to help advance appropriate patient use,
- (b) provide technical, scientific and educational information,
- (c) support medical research and education, and
- (d) obtain feedback and advice about our products through consultation with medical experts.

In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirements. Esaote is also concerned that the interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large. To this effect, Esaote adopted the procedure "Interactions with Healthcare Organizations and Healthcare Professionals", included in this MSGA.

Esaote Anti-Corruption Regulations are to reinforce Esaote's intention that its interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine. The mentioned Esaote Anti-Corruption Regulations are based on the principle that healthcare professionals' care of patients should be based, and should be perceived as

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being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

In order to structure adequate processes and provide for behavior rules for the relationships with Key Opinion Leaders, Esaote adopted the "Key Opinion Leaders Guidelines", included in this MSGA.

For this reason Esaote Anti-Corruption Regulations contain specific sections aimed at providing the regulation on the interactions with healthcare professionals concerning:

- (a) the possibility to grant modest gifts and the reimbursement of travel and hospitality expenses to healthcare professionals during demonstrations or training events (see the Procedure on Gifts, Travel, Hospitality and Expenses of third parties and Key Opinion Leaders Guidelines);
- (b) the Group support to third-party educational conferences/initiatives, the making of charitable donations and the providing of medical devices for charity/evaluation/demonstration purposes (see the Procedure on Sponsorship agreements and Donations and Key Opinion Leaders Guidelines);
- (c) the possibility to execute consulting agreements with healthcare professionals (see the Procedure on Third Parties and Key Opinion Leaders Guidelines).

#### 8 GIFTS, EXPENSES AND HOSPITALITY — OFFERED AND RECEIVED

Gifts or any other financial or other benefits can be either made or received where it is in the context of a commercial courtesy, and it does not compromise the integrity and/or reputation of either party, and cannot be construed by an impartial observer as aimed at creating an indebtedness or obtaining undue advantages.

Gifts and other financial advantages or other benefits made or received must therefore be reasonable and *bona fide* in all circumstances. In any case all gifts and financial advantages or other benefits made or received must be in accordance with Esaote's internal rules and must be recorded and supported by appropriated documentation.

Any gift, financial advantage or other benefit must have all the following characteristics. It must:

- (a) not be a cash payment;
- (b) be provided in connection with a bona fide and legitimate business purpose;
- (c) not be motivated by a desire to exert improper influence, or the expectation of reciprocity;
- (d) be reasonable under the circumstances;
- (e) be tasteful and commensurate with generally accepted standards for professional courtesy; and
- (f) comply with the local laws and regulations that apply to the Public Official and private party.

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### 8.1 Gifts, financial advantages or other benefits offered to, or received by, Esaote Personnel

As stated above in Section 8, any gifts, financial advantage or other benefit offered to, or received by Esaote Personnel must, from an objective viewpoint, be reasonable and *bona fide*.

Anyone who receives offers of gifts or hospitality treatment or financial advantage or other benefit that cannot be considered as commercial courtesy of small value, shall reject them and immediately inform: (i) the direct supervisor or the Business Partner's primary contact at Esaote; and/or (ii) the Esaote Compliance Officer.

### 8.2 Gifts, financial advantages or other benefits provided to third parties (including Public Officials)

As stated above in Section 8, any gifts, financial advantage or other benefit provided by any Esaote Personnel to a Public Official or any private party must, from an objective viewpoint, be reasonable and *bona fide*.

Any gifts, financial advantage or other benefit is reasonable and *bona fide* expenditure when it is an expense, such as transportation and lodging, that is directly related to:

- (i) the promotion, demonstration, or explanation of products or services; or
- (ii) the execution or performance of a contract with a government or governmental agency; or
- (iii) the attendance at educational seminars or workshops; or
- (iv) in furtherance of developing or maintaining cordial business relationships.

Reasonable and *bona fide* expenditures must be approved pursuant to the Esaote Procedure on gifts, travel, hospitality and expenses of third parties. These expenditures must be recorded accurately and transparently in the company's financial information with sufficient detail and supporting documentation to identify each recipient's name and title, the name and title of each beneficiary and the purpose of the payment or other benefit.

Any gift, hospitality or other benefit for a Family Member or designee of a Business Partner or of a Public Official or of a private party that was proposed at the request of a Business Partner or Public Official or as a result of the recipient's relationship to a Business Partner or Public Official must be treated as a benefit to that Business Partner or Public Official and is therefore subject to the restrictions provided by this MSG and the relevant Procedure on Gifts, Travel, Hospitality and Expenses of third parties .

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#### 9 BUSINESS PARTNERS

#### 9.1 Requirements for agreements with Business Partners

Esaote expects all of its Business Partners to comply with all applicable laws, including the Anti-Corruption Laws, in connection with Esaote's business.

Esaote may be held liable for corrupt activities on the part of its Business Partners. In particular, Esaote Personnel must comply with the provisions set out in this MSG and the other relevant Procedures (in particular the Procedures on Joint Venture and on Third Parties).

Business Partners must enter into written agreements before doing any work for or on behalf of Esaote and may be paid only in accordance with the terms of such agreement. All written agreements with Business Partners must

include reasonable and appropriate compensation and compliance terms.

Esaote requires that contracts with Business Partners include provisions requiring the Business Partners, among other things, to:

- (a) comply with the relevant Anti-Corruption Laws and this MSG and, for at high risk Business Partners (such as Intermediaries and Joint Ventures), have in place, and maintain throughout the term of the contract, their own regulations to ensure compliance;
- (b) in case of sub-contracting:
  - obtain Esaote's prior approval of any sub-contractor (such as sub-agent, sub-representative, sub-Consultant or any other similar third party) in accordance with Esaote's internal rules;
  - ensure that any sub-contractor performing services in connection with the contract does so only on the basis of a written contract which imposes on and secures from such party terms equivalent to those imposed on the Business Partner;
- (c) promptly report to Esaote any request or demand for any undue financial or other advantage of any kind received by the Business Partner in connection with the performance of the contract;
- (d) in the event that Esaote has a reasonable belief that the Business Partner may have violated the compliance-related provisions of the contract, allow Esaote to have an audit carried out over the Business Partner;
- (e) Esaote's right to terminate or suspend the execution of the agreement and to receive compensation of damages in case of breach of the obligations, representations and warranties referred to above and/or violation of the Anti-Corruption Laws.

When the Business Partner is:

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- an Intermediary, the provisions of Section 9.2 shall apply;
- a Consultant, the provisions of Section 9.3 shall apply;
- a Joint Venture partner, the provisions of Section 9.4 shall apply.

In relation to other Business Partners, upon the detailed written request of the interested Esaote business unit, the Esaote Compliance Officer will consider and, if appropriate, advice the Esaote business unit which exceptions may be authorized in respect of the provisions of the Anti-Corruption Regulations with reference to the due diligence aimed at identifying specific anti-corruption Red Flags and the approval process of Business Partners.

#### 9.2 Intermediaries

Agreements with Intermediaries may raise anti-corruption issues and must be negotiated, entered into and managed in compliance with the Esaote Procedure on Third Parties.

The Esaote Procedure on Third Parties must be compliant with the following minimum standards:

- (a) the Intermediary shall be of outstanding reputation for honesty and correct business practices and high ethical standing and, when the Intermediary is a company, not recently incorporated;
- (b) an Intermediary selection internal regulation providing for an appropriate level of due diligence (aimed at identifying specific anti-corruption Red Flags) on the potential Intermediary must be implemented;
- (c) the selection of the Intermediary and the stipulation of the Intermediary agreement must be approved in compliance with approval proceedings;
- (d) the Intermediary agreement must be in writing and must also contain:
  - (i) a description of the service to be provided by the Intermediary;
  - (ii) a requirement that the Intermediary shall at all times comply with the Anti-Corruption Laws and this MSG and shall have and maintain in place throughout the duration of the Intermediary agreement its own regulations to ensure compliance;
  - (iii) a requirement to promptly report to Esaote any request or demand for any undue financial or other advantage of any kind received by the Intermediary in connection with the performance of the Intermediary agreement;
  - (iv) a requirement that the Intermediary shall ensure that any person associated with the Intermediary and who is performing services in connection with the Intermediary agreement do so only on the basis of a written contract with imposes on and secures from such persons terms equivalent to those imposed on the Intermediary;
  - (v) the currency and amount of the compensation, which must be proportional to the subject matter of the agreement, to the experience of the Intermediary and to the country where the services will be carried out;

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- (vi) the representation and covenant of the Intermediary that the compensation payable pursuant to the Intermediary agreement shall be used solely as payment for its professional services and that no part thereof shall be given to a Public Official or private party or to any of his/her Family Members, for corrupt purposes or to the counterparty with which Esaote wishes to conclude the deal, in each case through the Intermediary service in violation of applicable laws;
- (vii) a prohibition on the Intermediary transferring, either directly or indirectly, the compensation to directors, officers, members of the corporate bodies, or employees of Esaote or to any of their Family Members;
- (viii) the billing terms (or methods for payment) and payment terms, taking into account that:
  - payment shall not be made to a party other than the Intermediary or to a country other than the country of one of the parties or where the agreement shall be implemented;
  - payment shall be subject to collection by Esaote when the services to be provided
    by the Intermediary are aimed at the conclusion of a deal that will bring earning of
    money for Esaote or, in all other cases, to the conclusion of the contract to which
    the Intermediary's service refers to;
  - payment shall be made directly and exclusively on the registered account of the intermediary and never to numbered accounts or in cash;
- (ix) the commitment of the Intermediary to notify the Contract Holder of any changes that have occurred in its ownership and/or in respect of the representations provided to Esaote during the selection phase and/or in respect of anything that could have a bearing on the ability of the Intermediary to conduct activities pursuant to the contract;
- (x) Esaote's right to carry out audit on the Intermediary and to terminate the agreement in case of a change of control of the Intermediary;
- (xi) a clause providing for the non-transferability of the agreement;
- (xii) the representation and covenant of the Intermediary that, at the time of signing of the agreement and for so long as the agreement is in effect, neither he/she nor his/her Family Members, nor, when the Intermediary is a company, its owners, directors, employees, nor the company itself, are or will be Public Officials;
- (xiii) the clause entitled "Corporate Liability" that Esaote S.p.A. and its Subsidiaries are required to insert in contracts bearing their signature; and
- (xiv) Esaote's right to terminate the agreement and to interrupt the payment and to receive compensation for damages in case of breach of the obligations, representations and warranties referred to above and/or violation of the Anti-Corruption Laws or the Esaote Procedure on Intermediaries and Consultants;

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- (e) performance of the agreement by the Intermediary to be continuously and appropriately monitored by the Contract Holder, in order to assure that the Intermediary always acts in compliance with the Anti-Corruption Laws, this MSG and the Esaote Procedure on Intermediaries and Consultants;
- (f) the amount paid according to the Intermediary agreement must be properly and transparently recorded in Esaote's books and records;
- (g) payments are made exclusively subject to the control that the service has been rendered and/or that the conditions foreseen in the agreement concerning payment of the fees have been met; and
- (h) the original documentation related to the selection and approval of the Intermediary and the Intermediary agreement and the controls for verifying compliance with the Esaote Procedure on Intermediaries and Consultants must to be kept for at least 10 years.

#### 9.3 Consultants

Esaote expects all its Consultants to comply with all applicable laws, including the Anti-Corruption Laws.

Esaote may be held liable for corrupt activities on the part of its Consultants and thus imposes special requirements to be adopted in connection with Consultants.

In particular, contracts with Consultants must be negotiated, entered into and managed in compliance with the Esaote's Procedure on Third Parties.

The Esaote's Procedure on Third Parties must be compliant with the following minimum standards:

- (a) the Consultant shall be of outstanding reputation for honesty and correct business practices and high ethical standing;
- (b) Consultant selection process providing for an appropriate level of due diligence (aimed at identifying specific anti-corruption Red Flags) on the potential Consultant must be implemented. The due diligence should at least comprise what follows:
  - (i) establishing the identity of the Consultant;
  - (ii) confirming the scope of services;
  - (iii) establishing whether the Consultant has any links to Public Officials;
  - (iv) establishing whether the Consultant has been subject to any allegations, investigations and/or convictions relating to bribery or corruption, or to other criminal activities;
- (c) the selection of the Consultant and the stipulation of the consulting agreement must be approved in compliance with approval proceedings;
- (d) the consulting agreement must be in writing and must also contain:

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- the Consultant's declaration that the amount paid is only the payment for the performance of the activities described in the contract and provided that these sums will never be transmitted or used for bribing purposes;
- (ii) the billing (or methods of payment) and payment terms, taking into account that (i) such payments may be made only in favour of the Consultant and to the consultant's country of incorporation, only to the registered account of the Consultant as indicated in the contract and never on numbered accounts or in cash, and (ii) the early payment of the fee (before the complete execution of the contract terms) may be allowed only in specific cases (properly motivated and stated in the contract) and, in any event, only for a part of the entire amount;
- (iii) the commitment of the Consultant to comply with the applicable laws, and in particular the Anti-Corruption Laws, and this MSG, to register in its books and records fairly and transparently the amount received and, based on the level of risk of Consultants, to have in place and maintain throughout the term of the contract its own regulations to ensure compliance;
- (iv) a requirement to promptly report to Esaote any request or demand for any undue financial or other advantage of any kind received by the Consultant in connection with the performance of the contract;
- (v) the right for Esaote to carry out audits on the Consultant in the case where Esaote has a reasonable suspicion that the Consultant may have violated the provisions of the contract referred to above;
- (vi) the clause entitled "Corporate Liability" that Esaote S.p.A. and its Subsidiaries are required to insert in contracts bearing their signature;
- (vii) Esaote's right to terminate the agreement and to interrupt the payment and to receive compensation of damages in case of breach of the obligations, representations and warranties referred to above and/or violation of the Anti-Corruption Laws.

#### 9.4 Joint Ventures

Esaote may be held liable for corrupt activities on the part of its partners in Joint Ventures and must take steps to cause even Joint Ventures in which it is not the controlling partner to implement adequate internal control policies.

Before Esaote S.p.A. or any of its Subsidiaries enters into a new Joint Venture, they must follow the due diligence aimed at identifying specific anti-corruption Red Flags and approval internal processes set out in the Esaote Procedure on Joint Venture agreements.

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All Joint Ventures agreements must be negotiated, entered into and managed in compliance with the Esaote Procedure on Joint Venture agreements.

The Esaote Procedure on Joint Venture agreements must be compliant with the following minimum standards:

- (a) the partners of the Joint Venture shall be only entities who are well-known, reliable and with outstanding reputation for honesty and correct business practices;
- (b) an approval internal regulation must be implemented providing for a documented and appropriate level of due diligence (aimed at identifying specific anti-corruption Red Flags) review on each of the partners of the Joint Venture and on the contractual arrangements for the operations of the Joint Venture;
- (c) in cases where Esaote does not control the Joint Venture, Esaote representatives acting within the Joint Venture shall use their best efforts to cause the Joint Venture to operate in compliance with the principles described in this MSG;
- (d) Esaote Personnel, in negotiating the Joint Venture agreement, shall use best efforts to include in such agreement the following provisions:
  - the commitment by the Joint Venture's operator to adopt and the commitment by each partner to cause the Joint Venture to adopt an effective and appropriate internal control system and a compliance program for the prevention of corruption and money laundering;
  - (ii) the commitment by the Joint Venture's operator to act and the commitment by each partner to cause the Joint Venture to act in compliance with the Anti-Corruption Laws, the internal control system and the compliance program;
  - (iii) the commitment by each partner that in all activities directly or indirectly related to the Joint Venture, the partners and the Joint Venture shall never pay bribes to Public Officials or to any other private party or their Family Members or to directors or members of the corporate bodies or to employees of the counterparty with which the Joint Venture proposes to operate;
  - (iv) Esaote's right to have an audit carried out on the Joint Venture or on the Joint Venture's operator in the event that Esaote has a reasonable belief that the Joint Venture or the Joint Venture's operator (in its activities directly or indirectly related to the Joint Venture) may have violated the Anti-Corruption Laws or paid bribes to Public Officials or to any other private party or their Family Members or to directors or members of the corporate bodies or employees of the counterparty with which the Joint Venture proposes to operate;
  - (v) the clause entitled "Corporate Liability" that Esaote S.p.A. and its Subsidiaries are required to insert in contracts bearing their signature;

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- (vi) Esaote's right to terminate the Joint Venture and to receive compensation for damages in case of breach of the anti-corruption obligation of the Joint Venture agreement or in case of the violations of the Anti-Corruption Laws or of the related policy in the Joint Venture;
- (e) the original documentation related to the selection and approval of the partners, the Joint Venture agreement and the controls for verifying compliance with this MSG must be kept for at least 10 years;
- (f) the activities of each Joint Venture and Joint Venture's operator must be constantly monitored. Esaote's representative in the Joint Venture must promptly inform the Esaote Compliance Officer in relation of any news concerning an investigation or ascertained violation of Anti-Corruption Laws by the operator of the Joint Venture, the Joint Venture partners, their owners, members of their corporate bodies or their representatives in the Joint Venture.

#### 9.5 Preliminary evaluation of deviations

Any deviation, for specific cases, from the terms set out in this Section 9, must be subject to the preliminary evaluation by the Compliance Officer on the basis of a written and detailed note submitted by the relevant business unit.

#### 10 THIRD PARTIES/SUPPLIERS

Esaote may be held liable for corrupt activities on the part of Suppliers performing services for or on behalf of Esaote and their sub-suppliers. It is therefore a requirement for Esaote's vendors to comply with the ethics standards and qualification requisites established by Esaote.

Esaote sets out roles and responsibilities of the main parties involved in the procurement process and defines general rules for key activities that cut across the procurement process, such as vendors management, procurement reporting and control and document management.

The mentioned key activities must be carried out in accordance with the Anti-Corruption principles described in this MSG, with particular reference, *inter alia*, to the vendors' selection and qualification process, contract award, post-award contract management, contract standard protection clauses, including undertakings of compliance with Anti-Corruption Laws and monitoring of Suppliers' ethical requirements. Furthermore, when a Supplier is a Business Partner, the principles under Section 9 shall also apply.

#### 11 POLITICAL CONTRIBUTIONS

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Political contributions could constitute corruption offences and therefore present a risk of consequent liability. The risks arising from political contributions are that they may be used by a company as an improper means for bribery to retain or obtain a business advantage such as to win a contract, obtain a permit or licence, or shape legislation favourable to the business.

Because of these risks, Esaote does not permit any direct or indirect contributions in whatever form to political parties, movements, committees, political organizations and trade unions, nor to their representatives and candidates (altogether, "Political Contributions"), except those specifically mandated by applicable laws and regulations. In case of any doubts as to the mandatory nature of the contribution, the Esaote Compliance Officer shall be consulted.

Political Contributions must be compliant with the following minimum standards:

- (a) all contributions must be approved by the Chief Executive Officer of Esaote S.p.A. and shall be made in accordance with the approved budget;
- (b) contributions shall be made only in favour of beneficiaries well-known, reliable and with outstanding reputation for honesty;
- (c) the beneficiary must show that it is an officially recognized entity in accordance with the applicable laws;
- (d) an adequate due diligence review aimed at identifying specific anti-corruption Red Flags on the beneficiary entity shall be carried out, to be subject to the evaluation of Esaote Compliance Officer;
- (e) legal opinion on the legitimacy and mandatory nature of the contribution under the applicable laws shall be forwarded to the Esaote Compliance Officer;
- (f) in line with the provisions of the relevant laws and Esaote's regulations, payments to the beneficiary entity must be made exclusively on the account registered in the name of the beneficiary entity; it is not permitted to make payments to numbered accounts or in cash, or to a party other than the beneficiary entity or to a third country other than the beneficiary entity's country;
- (g) contributions must be properly and transparently recorded in the company's books and records:
- (h) the beneficiary entity shall undertake to record properly and transparently the contributions received in its own books and records;
- (i) the original documentation related to the approval of the contribution and the controls of compliance with the relevant internal regulations must be kept for at least 10 years.

#### 12 CHARITABLE CONTRIBUTIONS/DONATIONS

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Donations to charities, government agencies and government instrumentalities present the risk of funds or something of value being diverted for the personal use or benefit of a Public Official or private party.

Even if a Public Official or private party does not receive a direct economic benefit, a legitimate charitable contribution made in exchange for obtaining or retaining business or to secure an improper advantage could be construed as an unlawful payment under the Anti-Corruption Laws.

All charitable contributions must be approved for anti-corruption compliance purposes and in compliance with the provisions of the Esaote Procedure on Sponsorship agreements and Donations.

The Esaote Procedure on Sponsorship agreements and Donations must be compliant with the following minimum standards:

- (a) all contributions must be approved by the Chief Executive Officer of Esaote S.p.A. and shall be made in accordance with the approved budget;
- (b) contributions shall be made only in favour of entities not recently incorporated, well-known, reliable and with outstanding reputation for honesty and correct business practices;
- (c) the beneficiary entity must show that it has all the certifications and has satisfied all the requirements for operating in compliance with applicable laws;
- (d) an appropriate internal regulation must be implemented which shall set out an approval process of contributions and, for the aim of such approval, shall provide for an adequate description of the nature and the scope of the single contribution, a due diligence review aimed at identifying specific anti-corruption Red Flags on the beneficiary entity and a check on the legitimacy of the contribution under the applicable laws;
- (e) in line with the provisions of the relevant laws and Esaote's regulations, payments to the beneficiary entity must be made exclusively on the account registered in the name of the beneficiary entity; it is not permitted to make payments to numbered accounts or in cash, or to a party other than the beneficiary entity or to a third country other than the beneficiary entity's country;
- (f) contributions must be properly and transparently recorded in the company's books and records;
- (g) the beneficiary entity shall undertake to record properly and transparently the contributions received in its own books and records;
- (h) the original documentation related to the approval of the contribution and the controls of compliance with the related policy must to be kept for at least 10 years; absence of conflict of interest has to be ensured (see Management of Conflict of Interest Guidelines.

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#### 13 SPONSORSHIP ACTIVITIES

Sponsorship activities may also raise anti-corruption issues. All sponsorship activities must be approved for anti-corruption compliance purposes in accordance with the Esaote Procedure on Sponsorship agreements and Donations.

The Esaote Procedure on Sponsorship agreements and Donations must be compliant with the following minimum standards:

- (a) all sponsorship activities must be approved by the Chief Executive Officer of Esaote S.p.A. and shall be made in accordance with the approved budget;
- (b) partners under sponsorship agreements shall only be entities or individuals who are well-known and reliable;
- (c) in the case of companies, a sponsorship agreement partner must prove that it has all the certifications and has satisfied all requirements for operating in compliance with applicable laws;
- (d) an appropriate internal regulation must be implemented which shall set out an approval process of sponsorship initiatives and, for the aim of such approval, shall provide for an adequate description of the nature and the scope of the single initiative, a due diligence review aimed at identifying specific anti-corruption Red Flags on the potential partner of the sponsorship agreement and a check on the legitimacy of the initiative under the applicable laws;
- (e) the sponsorship agreement must be in writing and must contain:
  - a declaration from the counterparty that the amount paid by Esaote shall solely be used as payment for the counterparty's services and that these sums shall never be given to a Public Official or a private party for corrupt purposes or transferred, either directly or indirectly, to members of the corporate bodies, directors, or employees of Esaote;
  - (ii) a declaration from the counterparty that at the signing of the agreement and during the implementation of it, neither the counterparty, nor, in case of a company, the company itself, or its owners, directors or employees are or will be Public Officials;
  - (iii) the currency and the amount paid pursuant to the sponsorship agreement;
  - (iv) the billing terms (or methods of payment) and payment terms, taking into account in line with the provisions of the relevant laws and Esaote's regulations that such payments can be made exclusively to the counterparty and in the country of counterparty's incorporation, exclusively on the account registered to the counterparty as indicated in the agreement and never to numbered accounts or in cash;
  - (v) the commitment of the counterparty to comply with the applicable laws, the Anti-Corruption Laws and the anti-corruption provisions of the relevant sponsorship

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- agreement and to record properly and transparently in its own books and records the amount received;
- (vi) the clause entitled "Corporate Liability" that Esaote S.p.A. and its Subsidiaries are required to insert in contracts bearing their signature;
- (vii) Esaote's right to terminate the agreement and to interrupt payments and receive compensation for damages in case of the counterparty's breach of the obligations, representations and warranties referred to above or violation of the Anti-Corruption Laws or of the relevant internal regulation on sponsorship agreement; and
- (viii) Esaote's right to carry out audit on the counterparty in the event that Esaote has a reasonable belief that the counterparty may have violated the compliance-related provisions of the relevant policy and/or of the agreement;
- (f) in line with the provisions of the relevant laws and Esaote's regulations, the amount paid according to the sponsorship agreement must be properly and transparently recorded in Esaote's books and records;
- (g) Esaote must ensure that payments are made exclusively as indicated in the sponsorship agreement, subject to the verification that the service has been rendered; and
- (h) the original documentation related to the approval internal regulation and the controls of compliance with the relevant policy must to be kept for at least 10 years;
- (i) absence of conflict of interest has to be ensured (see Management of Conflict of Interest Guidelines

#### 14 SELECTION OF PERSONNEL

Before Esaote appoints any new member of the board of directors or hires, appoints, transfers or promotes any new employee (i) who is likely to have Relevant Contact with a Public Official in connection with that member's or employee's work, (ii) who will supervise employees or Business Partners likely to have such contact, or (iii) who will be involved with financial controls issues or other activities covered by the Anti-Corruption Laws, Esaote must inquire about the individual's relevant background to the extent permissible under the applicable laws, in compliance with the anti-corruption provisions on selection and recruitment contained in Esaote's Procedure on the Selection of Personnel.

The process of selection of Personnel must include reference checks and appropriate questions regarding (a) any criminal record or indictment of the individual, and (b) any civil or administrative penalty or pending investigation relating to unethical or illegal activities of the individual, in accordance with and as permitted by applicable laws, and (c) any personal relationships with Public Officials.

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Absence of conflict of interest has to be ensured (see Management of Conflict of Interest Guidelines.

#### 15 ACQUISITIONS AND DISPOSALS

External (in the case of acquisitions) or internal (in the case of disposals) due diligence (including with respect to compliance with the Anti-Corruption Laws) aimed at identifying specific anti-corruption Red Flags is an important aspect of any proposed acquisition or disposals.

In relation to any proposed acquisition or disposals, Esaote's Compliance Officer must be consulted as far in advance as possible. Esaote's Compliance Officer and other counsel working on each such transaction will assist in identifying key risk factors and Red Flags to look for in acquisitions and in helping a Subsidiary that may be disposed of to prepare anti-bribery compliance information that a prospective purchaser may require, and in drafting anti-corruption representations and warranties for their inclusion in the relevant sale/purchase/merger agreement.

Whenever an acquisition is made by Esaote, a plan to comply with this MSG must be part of Esaote's post-acquisition integration plan. In addition, external or internal legal counsel working on an acquisition must advise the Esaote Compliance Officer of any new or increased existing anti-corruption risk to which the acquisition may expose Esaote, so that this MSG may be revised appropriately to protect Esaote from the anticipated new risk.

#### 16 ACCOUNTING POLICIES

Applicable laws, financial reporting and tax laws and regulations all require Esaote to keep accurate and complete accounting records of each business transaction. Esaote's records must conform to applicable accounting standards, and must completely and transparently reflect the facts of each transaction. All costs and charges, revenues and proceeds, receipts and payments and commitments have to be entered into the financial information in timely, complete and accurate form and have adequate support documents issued in conformity with any applicable legislation and the relevant internal control system provisions. All the book entries and related informative documentation have to be at disposal of the external auditor for the audit activities.

Consistently with the above requirements, it is Esaote's policy, that all payments by, and transactions of, Esaote, must be recorded accurately in the relevant company's books and records, such that Esaote's books, records and accounts accurately and fairly reflect its transactions and the sales and the acquisitions of its assets, in reasonable detail. This requirement applies to all transactions and expenses, whether or not they are material in an accounting sense. To this purpose, Esaote shall adopt, and keep updated, the relevant books, registers and accounting entries; Esaote's accounting handbooks define accounting principles as well as the accounts details to be

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adopted for such accounting entries. The circumstance that all the transactions are entered into the books in a true and fair form and that all the documentations are at disposal of the external auditor are reflected in the representation letter issued by Esaote entities to the external auditor.

#### 17 RECORDKEEPING AND INTERNAL CONTROLS

It is Esaote's policy, to establish and maintain adequate internal accounting controls sufficient to provide reasonable assurances that:

- (a) transactions are executed in accordance with management's general or specific authorization;
- (b) transactions are recorded as necessary:
  - (i) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements; and
  - (ii) to maintain accountability for all corporate assets;
- (c) access to assets is permitted only in accordance with management's general or specific authorization; and
- (d) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

On the basis of a top-down and risk based approach, focused on significant accounts, disclosures, entities and processes, Esaote maintains a system of internal controls related to financial information designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes, in accordance with generally accepted accounting principles, including those internal controls that:

- 1) monitor the regular maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the issuer;
- 2) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the issuer are being made only in accordance with relevant authorizations; and
- 3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or dispositions of issuer's assets that could have a material effect on the financial statements.

The reasonable assurance that the system of internal controls is intended to provide is the reduction to a low (remote) level of the risk that misstatements, caused by errors or fraud in amounts that

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would be material in relation to the annual financial statements or interim reports, may occur and not be detected on a timely basis.

The system of internal controls related to financial information consists of specific controls and pervasive controls, as defined below, at the different organizational levels, with different implementation methods.

Specific controls are performed during the normal course of operations to prevent, identify and correct errors and frauds. Typically, these controls include: accounting records documentation checks, authorizations issuance, reconciliation between internal and external information, consistency checks, etc. Considering their interrelations with operational activities, specific controls are also referred to as process-level controls.

Pervasive controls regard structural elements of the internal control system, constituting the general framework designed to ensure that process activities are performed and controlled in accordance with the objectives set by management. Usually, they encompass different regulations within the organization or specifically related to one or more of them. The principal types of pervasive controls include:

- (a) the assignment of powers and tasks at different levels, in keeping with the required degrees of responsibility, with special emphasis on key tasks and their assignment to qualified people;
- (b) the identification and segregation of incompatible activities/duties. This type of control involves the separation among the individuals that perform tasks, those who control them and those who authorize them. The segregation of duties (which sometimes requires the separation of functions) can be implemented not only through organizational tools, but also by separating physical areas (e.g. limited access to trading rooms) and defining profiles to access systems and data consistent with pre-established roles;
- (c) management control system, representing the set of organizational and methodological financial and non-financial (budgeting and reporting) measurement instruments, by means of which the management quantifies and address organization unit results, depending on specific targets.

#### 18 TRAINING OF ESAOTE PERSONNEL

Esaote Personnel shall be informed about the applicable Anti-Corruption Laws and the importance of compliance with those laws and this MSG, so that they can clearly understand and be aware of the different crimes, the risks, the relevant personal and corporate responsibilities and the actions to

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implement in order to contrast bribery and the potential penalties in case of violation of this MSG and Anti-Corruption Laws (both to the individuals concerned and Esaote).

In particular, all At-Risk Personnel are subject to a mandatory anti-corruption training program. To this purpose:

- (a) At-Risk Personnel shall receive a copy of this MSG and training on this MSG and relevant Anti-Corruption Laws within 90 (ninety) days of being hired or given new responsibilities, or, if it is not practicable for some reason, as soon as reasonably possible;
- (b) At-Risk Personnel should receive periodic refresher training:
  - (i) each At-Risk Personnel shall be responsible for keeping his or her training up to date;
  - (ii) each manager is responsible for ensuring that all At-Risk Personnel under his supervision complete training periodically;
- (c) the Human Resources Department is responsible for planning and providing training. It is also responsible for identifying and making the Esaote Compliance Officer aware of the recipients of the training and the kind of training to be provided;
- (d) the Human Resources Department collects the attendance records, the names and titles of participants, the results of self-testing, the copies of training materials and the dates of the training. It is responsible also for keeping all records in compliance with the applicable labour, privacy or other laws;
- (e) in defining and implementing the anti-corruption training program, the Human Resources Department must consult with the Esaote Compliance Officer for appropriate support and guidance in terms of the contents of the training materials and the carrying out of the training. The training program shall provide the necessary knowledge of the Anti-Corruption Laws and the instructions to recognize Red Flags and avoid ethically questionable actions. The program will assist the participants through the presentation of practical questions and scenarios that may occur in the course of the company operations.

#### 19 REPORTING

#### 19.1 Reporting requests

Any direct or indirect request by a Public Official or private parties for a payment (including a Facilitation Payment), gift, travel, meals or entertainment, employment, investment opportunities, personal discounts or other personal benefits other than reasonable and *bona fide* expenditures for the Public Official or private party or a Family Member or designee must be immediately reported to the direct supervisor (and to the 231 Supervisory Body) by the Esaote Personnel or the Business Partner who has received such request.

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The direct supervisor will be responsible for advising Esaote Personnel or the interested Business Partner on the proper course of action, which shall be in compliance with Anti-Corruption Laws and this MSG. To this purpose, the direct supervisor must consult with the Esaote Compliance Officer.

#### 19.2 Reporting Violations

Any suspected or known violation of the Anti-Corruption Laws or of this MSG must be reported immediately to one or more of the following:

- (a) the employee's direct supervisor or the Business Partner's primary contact at Esaote;
- (b) Esaote's Compliance Officer;
- (c) the 231 Supervisory Body;
- (d) the reporting channel under Esaote Code of Conduct

and, in any case, through the dedicated channels indicated in the Esaote Procedure on Ordinary Reporting and Confidential Reporting ("whistleblowing"), including the anonymous reports received by Esaote.

The direct supervisor, the Esaote Compliance Officer and the Human Resources Department will consult with each other to identify the proper course of action and they will assure the maintenance of the communication channels, the monitoring of received documents and the reporting of the results of the denunciations to the corporate control functions and bodies. Any disciplinary measure which will be implemented shall be in compliance with the Anti-Corruption Laws and this MSG.

Esaote Personnel will not be discharged, demoted, suspended, threatened, harassed, or discriminated against, in any manner, in the terms or conditions of employment, based upon any lawful and made in good faith reporting activity of such employee with respect to reporting of concerns regarding compliance with this MSG and/or the Anti-Corruption Laws.

#### 20 DISCIPLINARY ACTIONS AND CONTRACTUAL REMEDIES

Esaote shall use every reasonable effort in order to prevent any conduct in violation of Anti-Corruption Laws and/or this MSG and to interrupt and sanction any contrary conduct by Esaote Personnel.

Esaote will take appropriate disciplinary actions against any Esaote Personnel (i) whose actions are found to violate the Anti-Corruption Laws or this MSG, according to the Model 231 and collective

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employment agreements or other applicable national regulations, (ii) who fail to conduct or complete adequate training, and/or (iii) who unreasonably fail to detect or fail to report such violations or who retaliate against others who report such violations. Disciplinary actions may include the immediate termination of employment.

Esaote will take appropriate measures, including but not limited to termination of contract and claim for damages, against Business Partners whose actions are found to violate the Anti-Corruption Laws or this MSG. Contracts entered into by Esaote with Business Partners will include specific provisions to ensure compliance by Business Partners of the Anti-Corruption Laws and this MSG and to allow Esaote to take appropriate remedies, according to the Esaote Procedure on Standard contractual clauses to apply with Business Partners.

#### 21 MONITORING AND ENHANCEMENTS

The Esaote Compliance Officer shall monitor the adoption of this MSG and oversight the training of Esaote Personnel.

The Esaote Compliance Officer must periodically review this MSG to ensure that it remains maximally effective. In addition, the business units, the 231 Supervisory Body, the Internal Audit and the company's independent auditors should recommend enhancements to this MSG on the basis of emerging "best practices" or if gaps or weaknesses are identified.

If a violation is found, the Esaote Compliance Officer will evaluate whether MSG revisions or internal regulations enhancements would help prevent recurrence of the violation. In addition, each Subsidiary must respond appropriately to remedy any weakness in its compliance program.

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#### 1 INTRODUCTION

#### 1.1 Scope

This Procedure on Intermediaries and Consultants (the "**Procedure**") is part of the Esaote Procedures finalized to prevent bribery-related risks, provided for under the Management System Guideline Anti-Corruption.

The purpose of this Procedure is, firstly, to regulate the principles and rules to be followed by Esaote S.p.A. and its Subsidiaries in the negotiation, conclusion and execution of agreements with Third Parties and in particular with Intermediaries, as specified below.

#### This Procedure sets forth:

- what type of due diligence is necessary before a decision is made whether to enter into an Agreement with Third Parties;
- which clauses, representations and warranties must be included in contractual documentation with Intermediaries;
- how to implement adequate procedures and control systems once the Intermediary Agreement is established in order to prevent the commission of crimes of corruption and other crimes.

In this context, the following are the objectives of the application of this Procedure:

- to ensure that Esaote S.p.A. and its Subsidiaries retain and conclude Agreements with Third Parties with outstanding reputation for honesty and correct business practices, who share Esaote's ethical values and respect for the law, and who are ready to act only in accordance with Anti-Corruption Laws and international best practices;
- to ensure that the procedure of negotiation, conclusion and management of the Agreements with Third Parties are carried out according to criteria of diligence, transparency, correctness and in compliance with Anti-Corruption Laws, all applicable laws, the Code of Conduct, the Model and the Management System Guideline Anti-Corruption;
- to ensure the continuous updating and improvement of Esaote internal control system;
- to pursue criteria of pertinence and economic advantage.

Secondly, the purpose of this procedure is also to regulate the principles and rules to be followed by Esaote S.p.A. and its Subsidiaries in the negotiation, conclusion and execution of agreements with consultants. In this regard, the Procedure, in addition to the principles and rules concerning

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Intermediaries that have to be considered as applicable also to the relationships with consultants (unless otherwise specified) sets forth:

- the process of approval of the requests for a consultancy and the relevant roles and responsibilities;
- the detailed rules of the appointment of the consultants.

#### 1.2 Support

Details of applicable laws and Anti-Corruption Laws may change at any time, so it is important to obtain up-to-date legal advice before making any commitment on behalf of Esaote.

To this purpose must be directed to the Esaote Compliance Officer:

- questions with respect to the contents of Anti-Corruption Laws, the Code of Conduct, or any of the matters discussed in this Procedure, or their application to specific situations; and/or
- questions with respect to the financial information and internal controls provisions of the Anti- Corruption Laws, or any of the matters discussed in this Procedure, or their application to specific situations.

Should a recipient of this Procedure have doubts whether an agreement to be entered into with one party shall be ruled by this Procedure, or whether a subject can be considered or not a Third Party for the purposes of this Procedure and to evaluate if the relevant risk level presumes that a specific due diligence on the counterpart is carried out. the same recipient shall contact Esaote Group Compliance Officer, that shall take steps to evaluate whether the negotiation, stipulation and implementation of the agreement submitted to its attention is subject to this Procedure.

#### 2 APPLICATION

This Procedure has been prepared with the assistance and the supervision of the Compliance and Audit Committee and reviewed and approved by the Board of Directors of Esaote S.p.A.; its adoption and enforcement is mandatory for Esaote S.p.A. and all its Subsidiaries.

Moreover, Esaote will also use its influence, to the extent reasonable under the circumstances, to cause companies and entities in which Esaote has a non-controlling interest and business partners to meet the standards set up in this Procedure by adopting and maintaining an adequate system of internal controls consistent with the requirements established by the Anti-Corruption Laws. In any case, the representatives indicated by Esaote in such companies and entities shall use their best efforts to cause the standards set up in this Procedure to be adopted.

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Relevant circumstances include the degree of Esaote ownership of the company or entity (e.g. joint venture, consortia) and the laws and regulations governing the business operations in the country in which the company or entity is located or the activities are based.

#### 3 REFERENCE

- Code of Conduct;
- Model;
- "Management System Guideline Anti-Corruption".

#### 4 **DEFINITIONS**

When used in this Procedure, the following terms have the meanings set forth below:

**ANTI-CORRUPTION LAWS**: the Italian Criminal Code, the Legislative Decree 231 and other applicable provisions, the FCPA, the UK Bribery Act, other public and commercial anti-bribery laws in effect around the world, and international anti-corruption treaties such as the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions, and the United Nations Convention against Corruption.

**CODE OF CONDUCT**: Esaote's Code of Conduct.

**ESAOTE**: Esaote S.p.A. and its Subsidiaries.

**COMPLIANCE OFFICER**: A resource within the Company entrusted with the management and implementation of policies aimed at avoiding or reducing the exposure to liability for any violation of national or international regulations, decisions of competent authorities or other applicable rules of conduct. The Esaote Compliance Officer: (i) ensures knowledge of applicable regulations; (ii) makes proposals, preparation and update of compliance policies for preventing any corporate conduct that may be contrary to regulations; (iii) acts as reference person for Group companies; (iii) reports on the implementation and monitoring of compliance policies to the Board of Directors; (iv) assists the 231 Supervisory Body in relation to any Legislative Decree 231 issue; and (v) carries out communication and training on compliance policies.

**ESAOTE PERSONNEL**: the directors, officers, members of corporate bodies, managers and employees of Esaote.

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**FAMILY MEMBER**: the Public Official's spouse; the Public Official's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; the spouse of any of these people; and any other individuals who share the same household; and the private party's spouse; the private party's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; the spouse of any of these people; and any other individuals who share the same household.

FCPA: U.S. Foreign Corrupt Practices Act 1977, as amended from time to time.

**HUMAN RESOURCES DEPARTMENT:** The human resources department of Esaote S.p.A.

**INTERMEDIARY**: an independent individual or a company that Esaote proposes to retain to: (i) promote the commercial interests of Esaote and/or any of its Subsidiaries in relation to a single transaction/project; (ii) facilitate the stipulation and/or execution of contracts with third parties; and/or (iii) put in contact/introduce Esaote S.p.A. and/or any of its Subsidiaries to one or more other parties for the purpose of bringing/generating or retaining a business.

**DISTRIBUTOR:** natural person or legal entity that buy Esaote's products and sell them to the market.

**INTERMEDIARY AGREEMENT:** An agreement entered into by Esaote S.p.A. or any of its Subsidiaries with an Intermediary, or with a subject who, notwithstanding any definition to the contrary given by the parties, will carry out the activity of an Intermediary

**INTERNAL AUDIT:** If appointed, a professional/company appointed by Esaote S.p.A. responsible for the examination and independent evaluation of the internal control system, in order to verify the compliance with the requirements of the Management System Guideline Anti-Corruption, on the basis of its periodical audit plan approved by the Board of Directors of Esaote S.p.A. based on the preliminary opinion of the Audit and Compliance Committee.

**LEGISLATIVE DECREE 231**: Italian Legislative Decree June 8, 2001, No. 231, as amended from time to time.

**MANAGER:** The most senior manager of the department, of the area or of the operative company requiring the Intermediary services.

**MANAGEMENT SYSTEM GUIDELINE ANTI-CORRUPTION:** Esaote's Management System Guideline Anti-Corruption approved by the Board of Directors of Esaote S.p.A..

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**MODEL 231**: the Model concerning the organization, management and controlling activities of Esaote (ex Legislative Decree 231 of 2001) approved by the Board of Directors of Esaote S.p.A..

**NOTE:** The note drafted and signed by the Manager in accordance with Section 5.1.2.

**PRINCIPAL:** Each owner (partner or shareholder) of the Intermediary and of the Third Party, each member of the board of directors of the Intermediary and of the Third Party, each individual who is a beneficial owner of the Intermediary and of the Third Party, each individual who is able to exercise control over the Intermediary and over the Third Party, through any arrangement, and each individual (employees and consultants) working for the Intermediary and the Third Party, who is principally responsible for providing services in support of Esaote.

#### **PUBLIC OFFICIAL:**

- (a) anyone who performs public functions in a legislative, judicial or administrative capacity;
- (b) anyone acting in an official capacity for or on behalf of (i) a national, regional or local government, (ii) an agency, department or instrumentality of the European Union or of an Italian or a non-Italian national, regional or local government, (iii) an Italian or a non-Italian government-owned or government-controlled or government-participated company, (iv) a public international organization such as the European Bank for Reconstruction and Development, the International Bank for Reconstruction and Development, the International Monetary Fund, the World Bank, the United Nations or the World Trade Organization, or (v) an Italian or a non-Italian political party, member of a political party, official or candidate for political office;
- (c) anyone in charge of providing a public service, i.e. whoever performs a public service for whatever reason, where public service means an activity that is governed in the same way as a public function, except that the power vested in the latter is absent. The performance of basic ordinary tasks and exclusively manual work is excluded.

**SUBSIDIARY**: any entity that is directly or indirectly controlled by Esaote S.p.A.(1) in Italy and abroad.

**231 SUPERVISORY BODY:** the supervisory body (*Organismo di Vigilanza*) of Esaote S.p.A., as defined in Esaote Organizational Model and appointed pursuant to the Legislative Decree 231.

(1) The list of these companies is that included in the appendix "Controlled subsidiaries" of the most recent approved consolidated financial statement.

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**UK BRIBERY ACT:** The United Kingdom Bribery Act 2010 (and all associated secondary legislation), as amended from time to time.

#### 5 PROCEDURES AND RESPONSIBILITIES

In the case of one of a Function, within its area of responsibility, finds it necessary to enter into an Agreement with Intermediaries and with Third Parties, it must follow the due diligence and procedures set out below.

No Esaote Personnel may commit to or enter into an Intermediary Agreement and with Third Parties, without prior approval pursuant to the process established under this Section.

#### 5.1 Due Diligence on the Intermediary and on the Third Party

Before Esaote S.p.A. or any of its Subsidiaries enters into an Agreement with Third Parties a due diligence must be conducted on any potential Third Party.

The responsibility for the due diligence on the Third Party is given to the Manager.

#### 5.1.1 Standard Due Diligence Requirements

The due diligence shall be conducted by the Manager based on the following criteria:

- (a) the potential Third Party shall be asked to fill out the questionnaire attached to this Procedure as Attachment C (the "Questionnaire"), and to provide the relevant documents indicated therein;
- (b) the potential Third Party shall release an anti-corruption letter (the "Anti-Corruption Letter"), in the form of Attachment D. Esaote S.p.A. or the Subsidiary may tailor the Anti-Corruption Letter to meet the factual situation and include appropriate amenities;
- (c) further information shall be collected if it is believed to be appropriate in the particular circumstances, such as the importance of the project for which the Third Party is engaged, the risk of the country where the Third Party will operate and, in general, the perceived level of risk;
- (d) the potential Third Party's chain of control/ownership and the information collected shall be confirmed and verified through public sources, Internet or external sources (including Embassies, Consulates, international exchange agencies, Chambers of Commerce, etc.) according to the due diligence guidelines set out in Attachment A (the "Due Diligence Guidelines");

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(e) an important aspect in conducting the due diligence is attention to the red flags indicated in Attachment B (the "**Red Flags**").

#### 5.1.2 Drafting the Note

The data and information gathered through the due diligence exercise shall be adequately documented and collected in a Note drafted by the Manager and sent for consent according to the following Sections 5.2 and 5.3.

#### The Note shall also indicate:

- (a) the reasons for which the Third Party is considered essential or, in any case, useful for the conclusion of the particular deal for which the Intermediary has to be retained;
- (b) the reasons for which the services of the Third Party are to be considered inherent with the activities carried out by Esaote S.p.A. or its Subsidiary;
- (c) how the Third Party's selection procedure started, how the Intermediary's name came about, which external subject, if any, recommended the Third Party, and the Esaote business unit/area/operative company that received the recommendation and gave his/her name to the Manager;
- (d) how the real capabilities and competences of the Third Party have been verified with particular regards to: (i) the years of experience, (ii) in case of a company, the dimension of the company, (iii) the professional qualifications of the Intermediary and, in case of a company, the professional qualifications of its Principals, (iv) the reputation of the Third Party and/or of its Principals;
- (e) the declaration that due diligence was completed and that verifications were conducted in compliance with the principles contained in this Procedure, the Management System Guideline Anti-Corruption, and any other applicable Esaote Procedures and applicable laws;
- (f) a description of Red Flags or particular risks emerged or identified during the due diligence;
- (g) the names of the persons chosen according to Section 5.2 for conducting the negotiation in the name and on behalf of Esaote S.p.A. or its Subsidiary;
- (h) the declaration that the persons indicated under letter (g) above personally interviewed the Third Party (and, when it is a company, its legal representative and the individual who shall perform the services on behalf of Esaote S.p.A. or its Subsidiary) in view of the conclusion of the agreement and that, also in consideration of the results of the interview, there is no reason to believe that the Third Party has violated the Anti-Corruption Laws, and that he/she will violate them in the future;
- (i) the summary of the negotiations conducted with the Third Party to determine his/her/its compensation;
- (j) the detailed description of the service that the Third Party is required to provide;

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- (k) the amount of the compensation, the currency and the other payment conditions;
- (l) the reasons why the compensation can be considered adequate, also taken into account the experience of the Third Party and the Third Party's professional qualifications, the country where he/she/it will be working, the service indicated in the agreement, the workload and the difficulties of the services to be performed, any market references or international practices, and in any case, the profits expected to be generated from the project and/or its strategic nature in relation to the goods/services provided and to the country;
- (m) the currency and the tax implications for Esaote S.p.A. and/or its Subsidiaries connected to the Agreement with Third Party, if any;
- (n) information of any current, past or pre-existing relationship with the Third Party;
- (o) a list of the sources that have been used to verify the information contained in the Questionnaire and to conduct the due diligence.

In addition to the documents as specified above, the draft of the Intermediary Agreement shall be attached to the Note. The draft of the Intermediary Agreement shall contain the specific clauses indicated in the following Section 5.2

#### 5.2 Negotiations and contents of the Intermediary Agreement

The Intermediary Agreement shall be negotiated by at least two people, both chosen by the Manager, who shall not be part of the same corporate function, and shall not have a hierarchical relationship with each other.

The Intermediary Agreement, drafted in writing and according, when applicable, to the form under Attachment E (here attached as an example and as a legal protection), shall contain:

- (a) the name of the Intermediary (when it is a company, the name of the legal representative of the company, or, in the case of an agreement signed by a different individual, the deed granting signatory powers to the party);
- (b) the precise indication to the project, the business, the deal for which the Intermediary Agreement is to be retained;
- (c) the description of the services to be provided by the Intermediary;
- (d) the currency and amount of the compensation, which must be adequate as indicated in Section 5.1.2 letter (l) and which may also be defined as a percentage of the earnings to be derived from the deal for which the Intermediary service has been agreed upon;
- (e) the declaration of the Intermediary that he/she/it has implemented and that he/she/it will keep in place for the entire duration of this Agreement an effective and appropriate internal

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- control system and compliance program for the prevention of corruption, money laundering and other crimes;
- (f) the declaration of the Intermediary that neither he/she or his/her Family Members, nor, when the Intermediary is a company, its Principals are Public Officials and the commitment of the Intermediary to inform Esaote S.p.A. or the Subsidiary promptly: (i) if he/she, or any of his/her Family Members, or when the Intermediary is a company, any of its Principals, are appointed as Public Officials after entering into the Intermediary Agreement; (ii) of any event that could influence the circumstances pertaining to his/her own position or that of his/her Family Members or, when it is a company, that of its Principals as represented to Esaote S.p.A. or to its Subsidiary at the conclusion of the Intermediary Agreement. In the event of multi-years Intermediary Agreements, the above declaration is to be confirmed yearly or upon request of Esaote S.p.A. or of the Subsidiary;
- (g) the declaration of the Intermediary that he/she/it knows and commits to comply with applicable laws, Anti-Corruption Laws, the Management System Guideline Anti-Corruption, the Model, the Code of Conduct and this Procedure. In the event of multi-years Intermediary Agreements, the above declaration is to be confirmed yearly or upon request of Esaote S.p.A. or of the Subsidiary;
- (h) the commitment of the Intermediary to act and, in case of a company, to cause all of its directors, managers, employees and consultants who are responsible for providing services in support of Esaote to act in compliance with all applicable laws, the Anti-Corruption Laws, the Model, the Management System Guideline Anti-Corruption, the Code of Conduct and this Procedure;
- (i) the declaration and the obligation of the Intermediary that the compensation paid by Esaote S.p.A. or by the Subsidiary shall solely be used as payment for his/her/its professional services and that no portion of the compensation (i) shall ever be used to bribe, directly or indirectly, a Public Official or any of its Family Member and/or (ii) will be paid or redirected, directly or indirectly, to shareholders, partners, or members of the corporate bodies of the counterparty with which Esaote S.p.A. or its Subsidiary wishes to conclude the deal through the Intermediary service in violation of applicable laws, (iii) will be paid or redirected, directly or indirectly, to members of the corporate bodies, directors, or employees of Esaote or any of their Family Members;
- (j) when the Intermediary Agreement is also related to a third party's interest or when, vice versa, a third party has to enter into an Intermediary Agreement also for the benefit of Esaote, a mechanism that will attribute to the third party the relevant portion of the Intermediary's compensation; in that case the third party will also declare and warrant that its internal control system and compliance program are adequate to prevent any violation of Anti-Corruption Laws and are in line with the principles contained in this Procedure and the Code of Conduct;

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- (k) the billing terms or methods for payment, when the issuance of an invoice is not mandatory in the country where the payment has to be made;
- (l) the payment terms of the compensation, provided that (i) the payments as set forth in the Intermediary Agreement cannot be made to a party other than the counterparty of the Agreement or to a country other than the country of the parties of the Intermediary Agreement or other than the country where the services of the Intermediary shall be performed, (ii) when the services to be provided by the Intermediary are aimed at the conclusion of a deal that will bring earning of money for Esaote S.p.A. or for the Subsidiary, the payment of the Intermediary's compensation shall be subject to the collection by Esaote S.p.A. or by its Subsidiary, while, in all the other cases, the payment of the Intermediary's compensation shall be subject only to the conclusion of the agreement which the Intermediary's service refers to, (iii) the payments shall be made directly and exclusively in favor of the Intermediary by means of instructions to be given to the financial institutions on the account held in the name of the Intermediary (so-called delegation); instructions to local banks are permitted only in case any law, regulation or agreements require them as necessary, and in all cases, subject to notification to the competent administrative department;
- (m) the right of Esaote S.p.A. or of its Subsidiary to carry out controls, including audit and accounting controls on the Intermediary in the event that Esaote S.p.A. or its Subsidiary has a reasonable belief the Intermediary has violated Anti-Corruption Laws or its anti-corruption obligations under the Intermediary Agreement, and the commitment of the Intermediary to make available the documentation and information reasonably requested in relation to such controls and to keep the documentation concerning the services performed under the Intermediary Agreement for a reasonable period;
- (n) the right of Esaote S.p.A. or of the Subsidiary to disclose the contents of the Intermediary Agreement to other parties belonging to Esaote S.p.A. and to third parties, when there is a legitimate request, and the obligation of the Intermediary to provide those third parties with information on the contents of the Intermediary Agreement, upon request of Esaote S.p.A. or of its Subsidiary;
- (o) the prohibition on the Intermediary to undertake obligations on behalf of Esaote S.p.A. or of its Subsidiary;
- (p) the right of Esaote S.p.A. or of the Subsidiary to terminate the Intermediary Agreement in case of change of control of the Intermediary, if a company;
- (q) the non-transferability of the Intermediary Agreement or of some of the obligations and rights contained therein to third parties, without prior written approval of Esaote S.p.A. or of the Subsidiary;
- (r) an attachment containing a copy of the Code of Conduct, the Model, the Management System Guideline Anti-Corruption and this Procedure signed by the Intermediary;

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- (s) without prejudice to the provisions of the "Administrative Liability" clause, the right of Esaote S.p.A. or of the Subsidiary to terminate the Intermediary Agreement and to obtain compensation for damages, in an amount not less than the total of the compensation already paid, plus interests, in case of breach of the anti-corruption obligations, representations and warranties of the Intermediary Agreement or in case of violation of the Anti-Corruption Laws, the Code of Conduct, the Model, the Management System Guideline Anti-Corruption or this Procedure;
- (t) if reimbursement of travelling expenses and board has been agreed upon, a clause providing that these expenses may be reimbursed only upon Esaote S.p.A.'s or the Subsidiary's written approval and under the condition that they are reasonable and supported by adequate expense vouchers.

Depending on the circumstances of each transaction, the Manager and the Esaote Compliance Officer shall jointly assess, from time to time, the need or opportunity of obtaining independent statements or opinions confirming: (i) whether the contents, conclusion or performance of the Intermediary Agreement violate any Anti-Corruption Law, (ii) whether it is necessary to obtain a resolution or approval from any authority or any other subject for the conclusion or the performance of the Intermediary Agreement.

Depending on the circumstances of each transaction, the Manager shall also consult with the Esaote Compliance Officer before waiving or modifying any of the clauses provided for in the Intermediary Agreement under letter (a) to (t) above specifying the reasons for the request and the clauses to be modified or waived. The Esaote Compliance Officer will suggest to the Manager any possible actions/solutions.

#### 5.3 Evaluation and Decision

The Note drafted according to Section 5.1.2, including all its supporting documentation and draft of the Intermediary Agreement, shall be sent by the Manager to the Esaote Compliance Officer, which:

- (a) shall review the results of the due diligence on the basis of the Due Diligence Guidelines contained in Attachment A and the existence of possible Red Flags as indicated in Attachment B;
- (b) shall check if the draft of Intermediary Agreement effectively comply with the requirements provided for by this Procedure.

The Compliance Officer shall if necessary suggest to the Manager any appropriate further actions (e.g. conducting further due diligence).

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The Manager and the Esaote Compliance Officer may decide to appoint an external firm to conduct the due diligence as required by this Procedure.

The Manager shall transmit the Note, the result of the check by the Compliance Officer according to point (b) above and the outcome of any further action to the Board of Directors of Esaote S.p.A. or to the Board of Directors of the Subsidiary for approval.

If the scope of work of the Intermediary Agreement is to promote the commercial interests of Esaote and/or any of its Subsidiaries in relation to an undefined number of transactions/projects in a specific area and/or business (hereinafter referred to as, the "Intermediation Agreement"):

- (a) the Agency Agreement shall contain the precise indication of the duration of the agreement, which in no case can be more than three years;
- (b) any extension of the validity of the Agency Agreement shall be approved by the CEO;
- (c) any modification of the Intermerdiation Agreement shall require further approval by the CEO, unless this modification refers to a compensation to the Intermediary which is less onerous to Esaote (e.g. a lower percentage on the relevant contract price value).

(d)

#### 6 MANAGEMENT OF THE INTERMEDIARY AGREEMENT

#### 6.1 Choice of the Contract Manager

The management of the Intermediary Agreement is attributed to the Manager or to a manager who shall be chosen by the Manager (the "Contract Manager"). The Contract Manager shall be selected among individuals within Esaote Group with outstanding reputation for honesty and correct business practices as well as competence in the field of internal control systems.

The Contract Manager shall receive adequate training on Esaote's principles and rules of conduct, on Esaote's Code of Conduct, Model, the Management System Guideline Anti-Corruption, this Procedure and, in general, on the Anti-Corruption Laws.

#### 6.2 Duties of the Contract Manager

The Contract Manager is responsible for:

a) monitoring and ascertaining the correct execution of the Agreement with Third Parties, including issuance of the written authorization under article 6.3 hereinafter;

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- b) ascertaining and ensuring that the Third Party always operate according to criteria of maximum diligence, honesty, transparency, integrity and in compliance with the Anti-Corruption Laws, all applicable laws, this Procedure, the Management System Guideline Anti-Corruption, the Model or the Subsidiary organization, management and control model, as applicable, and the Code of Conduct;
- c) pointing out any possible Red Flags in the activities carried out by the Intermediary and immediately alerting the Compliance Officer;
- d) drafting a yearly report to be submitted to the Esaote Compliance Officer concerning the activities carried out according to the preceding points.

The activities indicated above may also be carried out upon request and with the support of the Esaote Compliance Officer.

#### 6.3 Accounting records and payments

Intermediary's compensation are recorded in a specific register called "Intermediary Compensation" and off-set in the credit side of the personal account opened for the Intermediary.

Payments are made: (a) subject to written authorization of the Contract Manager who shall confirm that the service has been rendered and/or that the conditions precedents set out in the Intermediary Agreement for payment of the compensation have been met, (b) only against invoices or written requests for payments from the Intermediary and in accordance with the contents of the Intermediary Agreement, and (c) exclusively on the bank account in the name of the Intermediary as indicated in the Intermediary Agreement, in accordance with the provisions contained in Section 5.2, letter (l).

It is not permitted to make payments to ciphered accounts or in cash, or to a party other than the counterparty of the Agreement with Third Parties, or in a country other than the parties' countries, or other than the country where the services have to be performed.

#### 7 CONSULTANTS

#### 7.1 Roles and Responsibilities

#### 7.1.1 Requesting Unit

The company's Units that need to have a Consultancy (hereinafter the Requesting Unit), has the responsibility to promptly identify the object needs.

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With reference to the scope of this procedure the Requesting Unite prepares the note "Consultancy Request for Approval" (hereinafter the Consultancy Note), submits it to the signature of its Manager and starts the approval process of the same.

Concluded the approval process the Requesting Unit activates the process of assignment of the consultancy, as indicated in paragraph 7.3.

#### 7.1.2 Consultancy Approver

Take on this role, subscribing the Consultancy Notes:

- (a) the direct reports of the CEO who evaluate all requests made by Requesting Unit hierarchically dependent and approve the consultancies for amounts not exceeding € 100,000 and with a duration not longer than 12 months;
- (b) CFO of Esaote, approving those not exceeding € 500,000;
- (c) the CEO, approving requests that exceed the limits of the powers of his/her direct reports.

In case between the Requesting Unit and the consultant indicated in the Consultancy Note are in progress other contractual relationships, for consultancies assigned in the previous 12 months, the level of the approval of the Consultancy Note will be the one resulting from the addition, both in reference to the time and the costs, of:

- (a) all tasks assigned by the Requesting Unit during the 12 months preceding the application; plus
- (b) the assignment of which is making the request,

all regardless of how the assignment of the same (new contract/revision). This event will be expressly stated by the Requesting Unit on the Consultancy Note, accompanied by the necessary evidence.

All the Consultancy Notes, regardless of the amount and the duration, to carry out an assessment on the purpose and scope of the consultancy, must be submitted in advance to:

- (a) the Responsible of the Unit that, with reference to the scope of the consultancy, has a role of guidance and control;
- (b) the Director of the Human Resources Department of Esaote, which also make his/her evaluation on the appropriateness of the consultancy required, in particular in relation to the total value of contracts assigned by the Esaote Group to that specific consultant (if indicated).

In the case of tasks to be entrusted to individuals that are former employees of the Esaote Group (for whatever reason there has been a termination of employment), the Human Resources Department also ensures the necessary assessments concerning employment law.

#### 7.1.3 Procurement Function

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As part of the activities for the assignment of consultancies, the Procurement Function, checks the identification of needs made by the Requesting Unit and, if it finds any inaccuracies, suspends the process and calls on the Requesting Unit to make the necessary adjustments.

For the purposes of the assignment of the consultancy (new contract/revision) the Procurement Function verifies the requirements of third party consultant to which the consultancy has been assigned in accordance with the provisions of the Management System Guidelines Anti -Corruption and of the paragraph 5.1 above.

#### 7.1.4 Compliance Officer

The Compliance Officer shall ensure the preparation and dissemination of reports relating to consultancy agreements assigned pursuant to this procedure, as indicated in par. 7.4.

#### 7.2 Drafting and approval of the Consultancy Note

The Consultancy Note shall contain:

- (a) the matter of the consultancy requested and the purpose of the activity;
- (b) the duration and the planned expenditures of the consultancy;
- (c) nature and reason of the request (e.g. the non-availability within the Company of appropriate resources, in terms of quantity and/or quality, to perform the required task, the lack of studies, information, project results, ongoing or concluded, useful and sufficient for the necessities required);
- (d) when and how to transfer within the company's know -how gained from the consultant;
- (e) method of assignment of the proposal that, alternatively, may be: (i) tender process, (ii) revision of an existing contract, in this case the it will also be highlighted the value/initial duration of the agreement and if there are already in progress other contractual relationships between the Requesting Unit and the consultant, (iii) direct assignment, in which case it shall be indicated the name of the consultant proposed, accompanied by an appropriate detail the characteristics/technical-professional references of the same and given evidence if there are already in progress other contractual relationships between the Requesting Unit and the consultant.

Defined this information, the Requesting Unit shall submit the Consultancy Note to the signing of its Manager and start the process of approval, precisely:

(i) the Requesting Unit shall obtain an opinion of the Responsible of the Unit that, with reference to the scope of the consultancy, has a role of guidance and control and of the Head of the Human Resources Department;

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(ii) thereafter, shall submit the Consultancy Note to the first position competent who assumes the role of Approver, that evaluates and approves the consultancy, within the limits of their delegation.

If the value of the consultancy requested exceeds the limits of the delegation of the first approver, the latter, acquired the above opinions, then also submit for approval the request of consultancy to the competent superior position.

#### 7.3 Assignment of the consultancy

Identified the need and after the above descrived approval process, the Requesting Unit starts the process of acquisition of the consultancy issuing, a proper request for purchase (RfP) and taking care that, in particular, the Consultancy Note, approved by all the subjects involved, is attached to the RfP.

The activities that follow the authorization of the RfP, by taking over the assignement and signing of the contract, are handled by the Procurement function that shall verify that:

- (a) consultancy engagements should be entrusted to third parties that possess high experience, certain professional characteristics and ethical correctness, verified in accordance with the provisions of the Management System Guidelines Anti -Corruption and of the paragraph 5.1 above;
- (b) the assignment of the consultancies should take into account that, over time, must be assured the plurality of sources of supply and that the number and value of services provided by a third shall not configure the relationship with the Company as the main or exclusive .

No activity can be assigned to third parties in the absence of a request duly formalized and approved and a contract/written assignment, formalized with the signing of a qualified attorney.

#### 8 REPORTING VIOLATIONS

Any suspected or known violation of the Anti-Corruption Laws and of this Procedure must be reported immediately to one or more of the following:

- the employee's direct supervisor or, in case of violation on the part of the Intermediary, the Contract Manager;
- the Compliance and Audit Committee;
- the Esaote Compliance Officer;
- the 231 Supervisory Body;
- in any case, through the dedicated channels indicated in the Esaote Procedure on Ordinary Reporting and Confidential Reporting ("whistleblowing").

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The direct supervisor, the Esaote Compliance Officer and the relevant Human Resources Department will consult to identify the course of action, including the application of disciplinary measures as appropriate.

#### 9 CONTROLS AND RECORD KEEPING

The original documentation related to the selection and approval of the Intermediary, the Intermediary Agreements and the controls of compliance with this Procedure is to be saved for 10 years as follows:

- for the Subsidiaries where a Esaote Compliance Officer is present: by the relevant Esaote Compliance Officer;
- for the other Subsidiaries: by the relevant Financial Officer.

#### 10 DISCIPLINARY ACTIONS

Esaote shall use every reasonable effort in order to prevent any conduct in violation of Anti-Corruption Laws and/or this Procedure and interrupt and sanction any conduct to the contrary of Esaote Personnel.

Esaote will take appropriate disciplinary action according to the Model and the collective employment agreements or other applicable national regulations, against any Esaote Personnel (i) whose actions are found to violate Anti-Corruption Laws or this Procedure, (ii) who unreasonably fail to detect or fail to report any violations according to the Management System Guideline Anti-Corruption or who retaliate against others who report such violations. Disciplinary action may include the immediate termination of employment.

#### 11 MONITORING AND ENHANCEMETS

The Compliance Officer is responsible for oversight of this Procedure.

The Compliance Officer must periodically review this Procedure to ensure that it remains effective. In addition, the Functions, Contract Manager(s), Compliance and Audit Committee, Internal Audit and the company's independent auditors should recommend enhancements to the Procedure if gaps or weaknesses are identified, and as emerging "best practices" develop.

If a violation is found, the Compliance Officer will determine whether Procedure revisions or procedural enhancements would help prevent recurrence of the violation.

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#### 12 ATTACHMENTS

These documents are part of this Procedure:

- Attachment A: "Due Diligence Guidelines";
- Attachment B: "Red Flags";
- Attachment C: "Intermediaries and Consultants Questionnaire";
- Attachment D: "Distributors Questionnaire";"
- Attachment E: "Contractors Questionnaire";"
- Attachment F: "Form of Anti-Corruption Letter";
- Attachment G: "Form of Intermediary Agreement".



#### ATTACHMENT A – DUE DILIGENCE GUIDELINES

In order to identify and document any reference to unethical or suspicious conduct of the potential Third Party, relationships with Public Officials and any information inconsistent with the one provided by the Third Party in the Questionnaire, the ownership and the information collected shall be reviewed and verified according to the following guidelines. The following is intended to suggest the appropriate steps. Additional investigations may be appropriate in certain circumstances.

- O Relevant names identification: as a first step, start by reviewing the Third Party's Questionnaire, registrations and other documents to identify the full name of the Third Party, any related entities (e.g. parent companies, subsidiaries, branches and affiliates) and Principals.
- Official registry of organizations: most official registries of companies and other organizations make their record available to the public in some form. Check ownership of companies etc., directorships, accounts and other relevant official documentation. Furthermore, if the owner is a trust company, check ownership of this company.
- Financial references: request that the official registries provide the financial statements (including the balance sheet and profit and loss statements) of the last three years of the Intermediary and of the related entities (in particular, the holding and the subsidiaries) and review them in order to verify, when possible, the information provided by the potential Intermediary. If audited financial records for the previous three years are not available, a third party financial referee may be requested to state the length of the relationship and provide an opinion of reliability, financial capabilities and probity.
- Qualifications and membership of professional bodies: review the *curricula vitae* provided by the Intermediary with the Questionnaire regarding the Principals and regarding managers, executives or key employees related to the contractual activity to be performed by the Intermediary and verify, when possible, the information disclosed; in particular the experience and qualifications of such people should be verified through the Intermediary's company's search, relevant professional associations, Internet resources or contacting the former employer when deemed useful or necessary. Most educational or professional bodies will confirm qualifications especially if the prospective employer or contractor is able to produce a letter of authority from the individual or company concerned. It is important to view originals of certificates issued by official bodies and, where these bodies are not well know, to assess the authenticity of the issuing body.

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- Electoral records, local government business records, etc: local government offices and business libraries will make available public records of individuals (e.g. from electoral roll records) and businesses (e.g. from local business directories, etc). Verify the Third Party is recorded at the address given.
- O **Criminal records**: check criminal records for the Third Party and related entities (parent companies, subsidiaries, branches and affiliates), Principals and key management personnel or individual (if legally permissible in the country concerned).
- O **Debarred or restricted parties lists:** information is available on some websites, and also via media searches, regarding companies and individuals barred from bidding on local national or international contracts. One such website with a debarred list for individuals and companies that have been judged to have committed acts of bribery or corruption in bid processes is the World Bank site: <a href="http://www.worldbank.org/html/opr/procure/debarr.html">http://www.worldbank.org/html/opr/procure/debarr.html</a>
- O Credit rating: there are a large number of international and local commercial organizations offering a credit rating services on individuals and organizations on a fee-paying basis. There are facilities available to check on bankruptcy or insolvency of individuals or companies. These will either be registers available to public scrutiny or listings made available on the Internet.
- O **Business history**: identify through Internet or financial statements or other sources the business history and experience of the Third Party. In this respect, verify the business history and experience of the Third Party also through the business references provided by the same in the Questionnaire.
- O Intermediary's experience with Esaote: review the list of the agreements the Intermediary currently has with Esaote or had in the past, if any. Subsequently, contact Esaote's key personnel that manages/managed each agreement, in order to request documentation on a previous Third Party's due diligence review if made and information regarding the Third Party's conduct in performing such agreements, and any Red Flags or issues arisen in connection to them.
- Media search: simple and cost-effective, the use of free and/or subscription databases to research the Third Party is recommended. If the Third Party has a website, this should be examined, as should useful government sites such as anti-cartel or anti-fraud, etc. In quotations, search each name on Google.com or comparable search engine. If the results are unreasonably large, click "search within results" and use appropriate terms to narrow the

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search, like: bribe, crime, charge, corrupt, fraud, slush fund, black money, money laundering. Search within the results using the narrowing terms individually. If the results remain unreasonably large, use the country to further narrow the search. Review the results list, identifying and printing any articles that implicate the Third Party, related entities or the Principals, in an inappropriate activity or indicate government services/employment or ties to the government or Public Officials, or that provide information that appears inconsistent with the information obtained through the Third Party's Questionnaire. Verify, if possible, such information also through other sources (including Embassies, Consulates, international exchange agencies, etc.)

O Anti-Corruption measures: search in the Third Party or related companies' official web-site codes, procedures or policies addressing business ethics, anti-corruption compliance, entertainment or gifts for clients or Public Officials.



#### ATTACHMENT B - RED FLAGS

The following are some of the Red Flags that are to be considered in conducting due diligence because they may indicate corruption. Although the presence of one or more Red Flags does not mean that improper conduct has already occurred or will occur, it does mandate greater scrutiny and implementation of safeguards.

- (a) The circumstances in which the Third Party was identified or introduced are unusual or abnormal (e.g.: the Intermediary was the only available Third Party, was introduced by someone who may be in conflict of interest, was strongly suggested by a government customer or a Public Official, was involved or proposed for no apparent good reason, etc.);
- (b) the Third Party carries out its business in a country or in an industrial sector with a reputation for bribery or corruption (be aware that the energy, construction and engineering industries are among those with a very high corruption risk). As to the country corruption risk please also refer to the Corruption Perceptions Index published by Transparency International (<a href="http://www.transparency.org/policy research/surveys indices/cpi">http://www.transparency.org/policy research/surveys indices/cpi</a>)(2);
- (c) the Third Party or any of its Principals is domiciled and/or is a resident of a so-called tax haven or of a country with a high rate of corruption;
- (d) the Third Party, if company, has an unusual corporate structure or was only recently incorporated;
- (e) the Third Party is duly registered but has no activity, no/poor staff, and its business address is only a "letter-box"
- (f) the Third Party is owned by or employs a Public Official or a Family Member's Public Official;

(2) Transparency International ("TI") is an international non-governmental organization dedicated to anticorruption efforts around the world. TI has more than 100 locally established national chapters and chaptersin-formation. These chapters work with governments, businesses and the media to promote transparency in elections, public administration, procurement and business. TI annually publishes a Corruption Perceptions Index ("CPI"). The CPI ranks more than 150 countries according to the degree to which corruption is perceived to exist among their public officials and politicians, ad determined by expert assessment and opinion survey.

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- (g) the Third Party or any of its Principals is in conflict of interest or has a questionable reputation or has been accused, prosecuted or convicted (especially in the case of bribery related offences, money-laundering or fraud) or has been debarred or blacklisted;
- (h) a third party representative suggests that the Third Party has or can make "special arrangements" with regard to the decision-making or action process at issue;
- (i) the Third Party refuses to certify compliance with the Anti-Corruption Laws;
- (j) the Third Party does not have an adequate internal control system nor adequate procedures for the prevention or identification of crimes of corruption and refuses to implement them;
- (k) the Third Party refuses to provide information requested during a due diligence review process;
- (l) the Third Party'sbusiness scope does not appear to be coherent/consistent with the contractual activity the Third Party will perform;
- (m) the Third Party does not have adequate resources to carry out the contractual activity or its financial situation (capital invested and turnover) is questionable (for example: annual turnover/net assets are less than the services provided, significant losses, financial statements not subjected to an independent audit, discrepancies or inconsistencies in the financial statements);
- (n) the Third Party has no/poor experience in relation to the contractual activity;
- (o) according to the Agreement with Third Parties, the transaction involves a Public Official or a public entity with a reputation for corruption or who requests a payment or gift;
- (p) the Third Party requests that payment under the Agreement with Third Parties to be paid: (i) in cash or; (ii) to an entity or individual rather than Intermediary; (iii) into a bank account registered in a country that is not the country where the Intermediary resides or where the Third Party provides services; (iv) into a ciphered bank account;
- (q) the Third Party requests for an increase in price, rather than a discount, for matters unrelated to a change in the agreement specifications or requirements, during negotiations;

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- (r) the Third Party requests for an unusual transaction structure, inclusion of incorrect or unnecessary cost items or false documentation;
- (s) other than as strictly provided for in the controlling contract, the Third Party requests for payment "up-front" or before completion of a project;
- (t) the Third Party does not provide directly the services but through one or more third parties companies or individuals;
- (u) the Third Party requests for unusually large payments, or payments that appear excessive and not reasonable in relation to the service to be rendered;
- (v) the Third Party requests for reimbursement of no/poorly documented expenses;
- (w) the Third Party gives incomplete or inaccurate information in required disclosures for false invoices or other documentation;
- (x) the laws of the country prohibit the use of a Third Party or restrict the form or amount of compensation.

The above list of Red Flags is not exhaustive. Other circumstances can arise that create a concern that corrupt activity may occur. Esaote Personnel who learn of circumstances that suggest the possibility of corruption should report the discovery of any such Red Flags immediately to the Esaote Compliance Officer.



#### ATTACHMENT C - INTERMEDIARIES AND CONSULTANTS QUESTIONNAIRE

For the purpose of this questionnaire please make reference to the definitions provided for in section 4 of the Esaote Procedure on Intermediaries.

The term "Principal" of the Intermediary means each owner (partner or shareholder) of the Intermediary, each member of the board of directors of the Intermediary, each officer or managing director of the Intermediary, each individual who is a beneficial owner of the Intermediary, each individual who is able to exercise control over the Intermediary through any arrangement, and each individual (employees and consultants) working for the Intermediary who is principally responsible for providing services in support of Esaote.

PLEASE SEE THE CHECKLIST AT THE END OF THIS APPLICATION FOR ADDITIONAL ITEMS THAT MUST BE SUBMITTED WITH YOUR APPLICATION. (PLEASE PROVIDE AN ENGLISH/ITALIAN TRANSLATION OF ANY DOCUMENT THAT IS IN ANOTHER LANGUAGE)

A.	CORP	ORATE INFO	ORMATIC	ON				
1.	Intermed	liary name:						
2.	VAT nur	mber/Fiscal co	de:					
3.	under th	which the serv e Intermediar ent will be per	у					
4.	Address	of the Interme	diary:					
Tele <sub>1</sub>	phone:				Fax	:		
E-m	ail:				Wel	bsite:		
5.	incorpo	k Place of Interpration/registra	tion		271			
		s the legal structure oration:		Intermediary	? (check o	Individu	ıal:	
	Othe	r:		ease scribe:				
N	ompliance D ISG Anti-Co nediaries, Co Distribu	orruption onsultants and	Approved	by the Board of I	Directors		PAGE 6 of 74	



Number of persons employed by your organization:

	Name	Title	Citizenship
		or the Intermediary: please describ what percentage of time the individ	
	Name	Title	Citizenship
В.	OWNER INFORMAte note that we need owner		
of the indirection portion layer separation owner equition identities acquired acquired that acquired that acquired that acquired that acquired that acquired that acquired the indirection of the indirect	the individual owners of the ectly through another legal on of the Intermediary, places as is necessary to identify that is traded on a pay in the relevant companyified here. If any sharehor reason, please also attach ared their shares through put ership (individual and/or but List owners of the Intermediate).	e Intermediary, whether an indivi- entity. If a business entity (corpor- ease trace ownership of all such by all ultimate individual owners of ched to this questionnaire. For ublic stock exchange, owners of fit or who are otherwise known to olders of less than five percent (a written statement confirming to ablic trading.	dual owns the shares directly ation, partnership, etc.) owns a entities back through as ma of such entities. Please do so any company in the chain ive percent (5%) or more of the relevant company must (5%) are not identified here if that all unidentified shareholds and 100%.
of the indirection portion layer separate owner equition that acquirection owners acquirection of the control o	the individual owners of the ectly through another legal on of the Intermediary, places as is necessary to identificate sheets of paper attackership that is traded on a pay in the relevant company iffied here. If any sharehor reason, please also attach red their shares through putership (individual and/or better the end of the e	e Intermediary, whether an indivi- entity. If a business entity (corpor- ease trace ownership of all such by all ultimate individual owners of ched to this questionnaire. For ublic stock exchange, owners of fit or or who are otherwise known to olders of less than five percent (a written statement confirming the ablic trading.	dual owns the shares directly ation, partnership, etc.) owns a entities back through as ma of such entities. Please do so any company in the chain ive percent (5%) or more of the relevant company must 5%) are not identified here that all unidentified shareholds.
of the indirection portion layer separate owner equition that acquirection owners acquirection of the control o	the individual owners of the ectly through another legal on of the Intermediary, places as is necessary to identify that is traded on a pay in the relevant companyified here. If any sharehor reason, please also attach ared their shares through put ership (individual and/or but List owners of the Intermediate).	e Intermediary, whether an indivi- entity. If a business entity (corpor- ease trace ownership of all such by all ultimate individual owners of ched to this questionnaire. For ublic stock exchange, owners of fit or who are otherwise known to olders of less than five percent (a written statement confirming to ablic trading.	ation, partnership, etc.) owns a entities back through as ma of such entities. Please do so any company in the chain ive percent (5%) or more of the relevant company must 5%) are not identified here final unidentified shareholds and 100%.



As part of our due diligence process, we need independent confirmation of the ownership information contained in your application. Please obtain a letter either from (i) your independent outside accountants or auditors, or (ii) a law firm, confirming the nership information set forth in your application or (iii) a form issued by

Are any other i	individuals able to e	exercise control	over the Interme	diary thro
arrangement?				·
Г		_		
Yes:			No:	
If the answer is	yes, please explain:			
List affiliated co	mnanies:			
	•			
(a) Parent co	ompany/ies (if any):			
	Jurisdiction of	Address	Telephone	Fax, w (if any) mail a
Full corporate Name	incorporation			IIIaii a
corporate	~-			for the

he Intermediary, if any):

Full corporate Name	Jurisdiction of incorporation	Address	Telephone	Fax, website (if any) and e- mail address

Sister owned company/ies (i.e., other companies owned by the parent company, (c) if any):

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Name	Jurisdiction of incorporation	Address	Telephon	e Fax, webs (if any) an mail addr
(d) Does or d	id any of these o	companies perform	n services on	hehalf of Esaote
	id any of these c			
Yes:			No:	
		pany and the activit		s or performed:
Compa	any		Activities	
			1	o:
held:		dentify the individu	al, the busines	ss and the positio
		dentify the individu	al, the busines	
held:		·	al, the busines	ss and the positio
BUSINESS HIS List any other agrethis question, "In	STORY AND R eements the Inter itermediary" also ermediary has ar	Business entity  EFERENCES  mediary has with Est includes all legal entity in the second and any	aate or had in	Position held  the past (for purph the Intermedian
BUSINESS HIS List any other agrethis question, "In owner of the Internal control of the Internal contr	story AND Remembers the Intertermediary" also ermediary has an ches and affiliate	Business entity  EFERENCES  mediary has with Est of includes all legal entity interest and any s):	aate or had in	Position held  the past (for purph the Intermedian



2.	List at least three business references (name, address, telephone, fax, e-mail address).
	Please provide references from companies with whom you have a relationship similar to
	the proposed relationship with Esaote.

	Full corporate name	Name of contact person and full	Telephone	Fax	E-mail address
а					
b					
c					

3. List one or more Banking/Credit References (name, address, telephone, fax, e-mail address):

	Full corporate name	Name of contact person and full	Telephone	Fax	E-mail address
d					
e					
f.					

4. Percentage of Intermediary's business which is or will be related to Esaote's business

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5.	Historical Backgro	oued.	
٥.	Thstorical Dackgro	Julia	
(a)		Intermediary has been in the in which you will work with half	
(b)	•	y, past or proposed changes in	as established, the primary areas ownership, changes, if any, of
D.	SCOPE OF WORK		
1.	the Intermediary Agreen		the business being contemplated in ture of such registration/license and opprovals.
2.	List, if any, all employ Intermediary to work o		ividuals or entities engaged by the
	Name	Title	Citizenship
3.	Please describe the ex- work on behalf of Esac		e Intermediary personnel who will
	Please provide the ca	urriculum vitae regarding each	Principal and each manager or
N	ompliance D. Lgs. 231  ASG Anti-Corruption nediaries, Consultants and Distributors	Approved by the Board of Directors	PAGE 31 of 74



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## MSG Anti-Corruption Third Parties

#### executive or key employee related to the contractual activity.

4.	Are there any laws, rules, regulations, or practices, in the area in which the services under the Intermediary Agreement will be performed, that impose a limitation on the services that may be performed by the Intermediary or on the amount or type of compensation that may be paid for such services?
	Yes: No:
	If the answer is yes, please explain:
E.	RELATIONSHIP WITH PUBLIC OFFICIALS
1.	Does any current or former Public Official or public entity have any ownership or other interest in the Intermediary?
	Yes: No:
	If the answer is yes, please identify the Public Official or the public entity:
2.	Is or was any Principal of the Intermediary a Public Official or is any Principal otherwise in a position to influence or provide services for a public entity?
	Yes: No:
	If the answer is yes, please identify the Principal and the position held as Public Official:
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3.	Is or was any Family Member of any Principal of the Intermediary a Public Official? (The term "Family Member of Principal" means the Principal's spouse; the Principal's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; the spouse of any of these people, and any other individuals who share the same household).					
	Yes	S:	No:			
		is yes, please identify the person's relationship to		ne of the person holding the ntermediary.		
4.		d the position or rank	held? Please indicate	Official, what is the name of e the dates of severance or		
		such service of dates of	the Principal's candida	icy.		
	Name of	Public entity	Position or rank he	·		
				·		
				·		
				·		
5.	Name of  Does the Intern	Public entity	Position or rank he	·		
5.	Name of  Does the Intern	Public entity  nediary have any kind	Position or rank he	eld Date of severance or		
<ol> <li>6.</li> </ol>	Name of  Does the Intern described above,  Could any of the	Public entity  nediary have any kind with Public Officials or situations as above illustrations.	Position or rank here I of business relation republic entities?	eld Date of severance or		
	Name of  Does the Intern described above,  Could any of the	Public entity  nediary have any kind with Public Officials or situations as above illusterest, with respect to the situations as above.	Position or rank here I of business relation republic entities?	Date of severance or a perception		

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F.

1.

2.

3.

## MSG Anti-Corruption Third Parties

Yes:	No:		
If the answer is yes, please identify the upon and their relationship to the Intern be required to fill out this form).			
FURTHER RELEVANT INFORM	MATION		
Does the Intermediary have written code anti-corruption compliance, entertainmer related topics? If yes, please attach.			
Yes:	No:		
In the past 5 (five) years, has the Intrassociated organization or any predecesse been (1) suspended from doing business with any criminal act, or (3) subject to corruption, tax evasion or other related act.	or organization), or ss in any capacity, o any allegation of f	any present or formed (2) investigated for	er Principal or charged
Yes:	No:		
If the answer is yes, please provide cor	nplete details (on a	separate sheet, if nec	essary):
Indicate the bank, branch, city and compensation under the Intermediary A			

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made in the Intermediary's name, to a bank in the Intermediary's home country or in the



	country in which the contractual activity will be	e carried out).	
4.	Please use this space to provide any additionato the relationship between the Intermediary a		y be relevant
	* * *		
679/2	te will process personal data received by the In 2016 – GDPR on personal data processing. I have information provided is accurate and complete	have reviewed this questionnaire,	and I declare
Na	me of the Intermediary S	ignature:	
Da	te: T	Typed name and title:	
	e ensure the following documents are attached ments in other languages):	d (and provide English/Italian tr	
	Document	:	Check if Attached:
Α.	Copy of company's search, incorporating establishment or incorporation of the Inter		1
В.	Copy of required registrations or other Intermediary to carry on the appropriate by		<b>↑</b>
C.	Independent confirmation of ownership de	ocumentation	1
D. Curriculum vitae of each Principals and of each managers or executive or key employees related to the Intermediary Agreement activity			

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Е.	Financial statements (audited, if available) for the prior three years, including balance sheets and profit and loss statements. If you cannot provide financial statements, please attach an explanation of why financial statements are not available	<b>↑</b>
F.	<b>Criminal records:</b> check criminal records for the Intermediary and related entities (parent companies, subsidiaries, branches and affiliates) Principals and key management personnel or individual (if legally permissible in the country concerned)	<b>↑</b>
G.	Anti-Corruption measures: procedures or policies addressing business ethics, anti-corruption compliance, entertainment or gifts for clients or Public Officials.	<b>↑</b>

Please-return the completed Questionnaire and all attachments to: [Name, title, address]



#### ATTACHMENT D – DISTRIBUTORS QUESTIONNAIRE

PLEASE SEE THE CHECKLIST AT THE END OF THIS APPLICATION FOR ADDITIONAL ITEMS THAT MUST BE SUBMITTED WITH YOUR APPLICATION. (PLEASE PROVIDE AN ENGLISH/ITALIAN TRANSLATION OF ANY DOCUMENT THAT IS IN ANOTHER LANGUAGE)

G.	CORP	ORATE INFO	ORMATIO	ON				
8.	Distribut	or name:						
	* 7 A /TT	• / <del>די</del> 1	1					
9.	VAT nui	mber/Fiscal co	de:					
10.	under th	which the serv e Distributor ent will be per						
11.	Address	of the Distribu	tor:					
Telep	phone:				Fax:			
E-ma	ail:				Website	<u>.</u> :		
12.	,	& Place of Distr pration/registra						
	b) What i	is the legal struc	ture of the	e Distributor? (	(check one)			
	Corp	oration:	Pa	artnership:		Individu	ıal:	
	Othe	r:		ease escribe:				
13.	Number	of persons emp	loyed by yo	our organization	n:			
14.		embers of the bo their citizenship:	ard of direc	ctors or other m	nanagers or exe	ecutives of	the Dis	tributor, their
		Name		Title		Ci	tizensł	nip
N	ompliance D ISG Anti-Co nediaries, Co Distribu	orruption onsultants and	Approved	by the Board of I	Directors		PAGE 7 of 74	



8 Management information for the Distributor: please describe the active management of the Distributor by position and what percentage of time the individual spends or will spend on Esaote business:

Name	Title	Citizenship

#### H. OWNER INFORMATION

Please note that we need ownership information concerning the Distributor that identifies all of the individual owners of the Distributor, whether an individual owns the shares directly or indirectly through another legal entity. If a business entity (corporation, partnership, etc.) owns any portion of the Distributor, please trace ownership of all such entities back through as many layers as is necessary to identify all ultimate individual owners of such entities. Please do so on separate sheets of paper attached to this questionnaire. For any company in the chain of ownership that is traded on a public stock exchange, owners of five percent (5%) or more of the equity in the relevant company or who are otherwise known to the relevant company must be identified here. If any shareholders of less than five percent (5%) are not identified here for that reason, please also attach a written statement confirming that all unidentified shareholders acquired their shares through public trading.

Ownership (individual and/or business entity percentages) must equal 100%.

#### 5. List owners of the Distributor

Name	Citizenship	% Ownership

As part of our due diligence process, we need independent confirmation of the ownership information contained in your application. Please obtain a letter either from (i) your independent outside accountants or auditors, or (ii) a law firm, confirming the ownership information set forth in your application, or (iii) a form issued by a government agency or entity verifying the current ownership of the company (i.e. Chamber of Commerce)

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Distributors

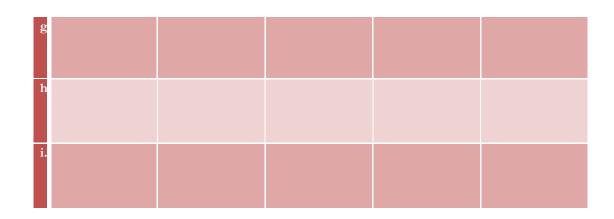
arrangement?				
Yes:			No:	
If the answer is	yes, please explain:			
List affiliated co	mpanies:			
(e) Parent co	ompany/ies (if any):			
Full corporate Name	Jurisdiction of incorporation	Address	Telephone	Fax, well (if any) a mail add
				+0# <del>13</del> #12
Full corporate	Jurisdiction of	Address	Telephone	
<b>-</b> _ <b>-</b> _ <b>-</b> _ <b>-</b> _ <b>-</b> _ <b>-</b> _ <b>-</b>	Lurisdiction	_ Addross	L Telephone	L Fox we
		Address	Telephone	(if any) a
corporate	of	Address	Telephone	Fax, we (if any) a mail add
corporate Name	of incorporation			(if any) a mail add
corporate Name  (g) Sister ow if any  Full corporate	of incorporation  oned company/ies (i. ):  Jurisdiction of	e., other comp	anies owned by th	(if any) a



	Company		Act	ivities	
	of the Principal business:	als of the Distrib	outor employed by	or do th	ney have an into
	Y	es:		N	o:
If the ans	wer above is y	ves, please identif	y the individual, th	ne busines	ss and the positi
	Individual	Bu	siness entity		Position held
List any o	other agreemention, "Distrib	utor" also includ	r has with Esaote of les all legal entities	s in whic	h the Distribut
	the Distribut es, branches a		est) and any relate	ed entitie	s (i.e. parent c
, as siaidi	ee, Statienes a	ara arrinaceo).			
	ame of	Esaote busine unit	ess Date		Type of
	eement				agreement (i
	eement	subsidiary			agreement (i

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8. List one or more Banking/Credit References (name, address, telephone, fax, e-mail address):

	Full corporate name	Name of contact person and full	Telephone	Fax	E-mail address
j.					
k					
1.					

9.	Percentage of Distributor's business which is
	or will be related to Esaote's business

10. Historical Background

(c) Number of years Distributor has been in the area of business in which you will work with Esaote or on its behalf

ea	
te	

(d) Briefly describe how and when the Distributor was established, the primary areas of business activity, past or proposed changes in ownership, changes, if any, of

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Distributors		



Distributors

	business activity, etc:		
J.	SCOPE OF WORK		
5.	the Distributor Agreement		ne business being contemplated in are of such registration/license and rovals.
6.	List, if any, all employees Distributor to work on bel		riduals or entities engaged by the
	Name	Title	Citizenship
7.	Please describe the experie on behalf of Esaote:	ence and qualifications of the D	istributor personnel who will work
	_	<i>iculum vitae</i> regarding each oyee related to the contractua	Principal and each manager or l activity.
8.	Distributor Agreement wi	ll be performed, that impose a l	rea in which the services under the limitation on the services that may of compensation that may be paid
	Yes:	No:	
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Intermediaries, Consultants and Distributors

### **MSG Anti-Corruption** Third Parties

	If the answer is yes, plea	se explain:		
K.	RELATIONSHIP W	VITH PUBLIC OFFICIAI	LS	
8.	Does any current or for interest in the Distribute		olic enti	ty have any ownership or oth
	Yes:		No:	
	If the answer is yes, plea	ase identify the Public Officia	al or the	public entity:
9.		of the Distributor a Public ( provide services for a public		or is any Principal otherwise in
	Yes:		No:	
	If the answer is yes, plea	ase identify the Principal and	the pos	ition held as Public Official:
10.	term "Family Member spouse's grandparents,	of Principal" means the Pr parents, siblings, children, n	incipal's	ributor a Public Official? (The spouse; the Principal's and the ephews, aunts, uncles, and first ndividuals who share the same
	Yes:		No:	
	ompliance D. Lgs. 231 MSG Anti-Corruption	Approved by the Board of Direc	ctors	PAGE 43 of 74



11.

12.

13.

14.

If the answer is yes, please identify the office held, the name of the person holding the office, and that person's relationship to the Principal of the Distributor.					
If any Principal of the employer and the retirement from such	position or rank h	neld? Please indica	ite the		
Name of	Public entity	Position or rank	k held	Date of se	verance or
Does the Distributor above, with Public C			, differer	nt from those	e described
Could any of the situ of a conflict of interest					
Yes:		No:			
Would the Distribut subcontractor) not a Distributor Agreeme	already mentioned a				
Yes:		No:			
If the answer is yes, upon and their relati be required to fill ou	ionship to the Distri				

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L.	FURTHER RELEVANT INFORMATION
1.	Does the Distributor have written codes, procedures or policies addressing business ethics, anti-corruption compliance, entertainment or gifts for clients or for Public Officials, or related topics? If yes, please attach.
	Yes: No:
2.	In the past 5 (five) years, has the Distributor (including any associated or previously associated organization or any predecessor organization), or any present or former Principal been (1) suspended from doing business in any capacity, (2) investigated for or charged with any criminal act, or (3) subject to any allegation of fraud, misrepresentation, bribery, corruption, tax evasion or other related activities?
	Yes: No:
	If the answer is yes, please provide complete details (on a separate sheet, if necessary):
3.	Indicate the bank, branch, city and country to which the Distributor would like compensation under the Distributor Agreement wire transferred. (Wire transfers will be made in the Distributor's name, to a bank in the Distributor's home country or in the country in which the contractual activity will be carried out).
4.	The Distributor executed a policy with a reputable insurance company against risks of damages, injuries or loss covering products under relevant Distribution Agreement and the Distributor's obligations.
5.	Please use this space to provide any additional information which you feel may be relevant

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	to the relationship between the Distributor and Esaote.	
	* * *	
679/2	te will process personal data received by the Distributor pursuant to Europea 016 – GDPR on personal data processing. I have reviewed this questionnaire, the information provided is accurate and complete to the best of my knowledge	and I declare
	me of the Distributor  Signature:	and benef.
Dat	e: Typed name and title:	
Dleace		
	ensure the following documents are attached (and provide English/Italian transmit in other languages):	ranslations of
	\ 1	canslations of  Check if  Attached:
	nents in other languages):	Check if
docun	Document:  Copy of company's search, incorporating document or other evidence of	Check if
A.	Document:  Copy of company's search, incorporating document or other evidence of establishment or incorporation of the Distributor  Copy of required registrations or other documentation authorizing the	Check if
A. B.	Document:  Copy of company's search, incorporating document or other evidence of establishment or incorporation of the Distributor  Copy of required registrations or other documentation authorizing the Distributor to carry on the appropriate business, if required by local law	Check if Attached:
A. B.	Document:  Copy of company's search, incorporating document or other evidence of establishment or incorporation of the Distributor  Copy of required registrations or other documentation authorizing the Distributor to carry on the appropriate business, if required by local law  Independent confirmation of ownership documentation  Curriculum vitae of each Principals and of each managers or executive	Check if Attached:

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G.	<b>Anti-Corruption measures:</b> procedures or policies addressing business ethics, anti-corruption compliance, entertainment or gifts for clients or Public Officials.	<b>↑</b>
н.	Policy with a reputable insurance company against risks of damages, injuries or loss covering products under relevant Distribution Agreement and the Distributor's obligations.	<b>↑</b>



Distributors

## MSG Anti-Corruption Third Parties

#### ATTACHMENT E - CONTRACTORS QUESTIONNAIRE

PLEASE SEE THE CHECKLIST AT THE END OF THIS APPLICATION FOR ADDITIONAL ITEMS THAT MUST BE SUBMITTED WITH YOUR APPLICATION. (PLEASE PROVIDE AN ENGLISH/ITALIAN TRANSLATION OF ANY DOCUMENT THAT IS IN ANOTHER LANGUAGE)

Μ.	CORPORATE INF	ORMATION				
15.	Contractor name:					
16.	VAT number/Fiscal c	ode:				
17.	Area in which the ser under the Contractor Agreement will be pe					
18.	Address of the Contrac	ctor:				
Tele	ephone:		Fax:			
E-m	nail:		Websi	te:		
19.	a) Date & Place of Con incorporation/registr					
	b) What is the legal stru	acture of the Contra	ctor? (check one)			
	Corporation:	Partnersh	nip:	Individu	al:	
	Other:	Please describe:				
20.	Number of persons em	ployed by your organ	nization:			
21.	List all members of the b titles and their citizenship		other managers or ex	xecutives of	the Contractor,	their
	Name	,	Title	Ci	tizenship	
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8 Management information for the Contractor: please describe the active management of the Contractor by position and what percentage of time the individual spends or will spend on Esaote business:

Name	Title	Citizenship

#### N. OWNER INFORMATION

Please note that we need ownership information concerning the Contractor that identifies all of the individual owners of the Contractor, whether an individual owns the shares directly or indirectly through another legal entity. If a business entity (corporation, partnership, etc.) owns any portion of the Contractor, please trace ownership of all such entities back through as many layers as is necessary to identify all ultimate individual owners of such entities. Please do so on separate sheets of paper attached to this questionnaire. For any company in the chain of ownership that is traded on a public stock exchange, owners of five percent (5%) or more of the equity in the relevant company or who are otherwise known to the relevant company must be identified here. If any shareholders of less than five percent (5%) are not identified here for that reason, please also attach a written statement confirming that all unidentified shareholders acquired their shares through public trading.

Ownership (individual and/or business entity percentages) must equal 100%.

#### 9. List owners of the Contractor

Name	Citizenship	% Ownership

As part of our due diligence process, we need independent confirmation of the ownership information contained in your application. Please obtain a letter either from (i) your independent outside accountants or auditors, or (ii) a law firm, confirming the ownership information set forth in your application, or (iii) a form issued by a government agency or entity verifying the current ownership of the company (i.e. Chamber of Commerce)

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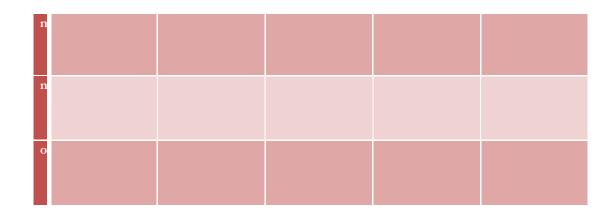
arrangement?		_		
Yes:			No:	
If the answer is ye	es, please explain:			
List affiliated com	npanies:			
(i) Parent con	npany/ies (if any):			
Full corporate Name	Jurisdiction of incorporation	Address	Telephone	Fax, we (if any) a mail ad
				for price
(j) Subsidiary Contractor,	company/ies (i.e if any):	., companies ov	wned, in whole	or in par
		., companies ov	wned, in whole  Telephone	Fax, we
Contractor,  Full corporate	If any):  Jurisdiction of	-		Fax, we (if any) a mail ad
Contractor,  Full corporate Name  (k) Sister own if any):  Full	If any):  Jurisdiction of incorporation  ed company/ies (i	Address	Telephone	Fax, we (if any) a mail ad
Contractor,  Full corporate Name  (k) Sister own if any):	Jurisdiction of incorporation  ed company/ies (i	Address  .e., other compa	Telephone  anies owned by the	Fax, we (if any) a mail ad
Contractor,  Full corporate Name  (k) Sister own if any):  Full corporate	Jurisdiction of incorporation  ed company/ies (i	Address  .e., other compa	Telephone  anies owned by the	Fax, we (if any) : mail ad
Contractor,  Full corporate Name  (k) Sister own if any):  Full corporate	Jurisdiction of incorporation  ed company/ies (i	Address  .e., other compa	Telephone  anies owned by the	Fax, we (if any) mail ad
Contractor,  Full corporate Name  (k) Sister own if any):  Full corporate Name	if any):  Jurisdiction of incorporation  ed company/ies (i	Address  e., other compa  Address	Telephone  anies owned by the  Telephone	Fax, we (if any) mail ad Fax, we (if any) mail ad
Contractor,  Full corporate Name  (k) Sister own if any):  Full corporate Name	Jurisdiction of incorporation  ed company/ies (i	Address  e., other compa  Address	Telephone  anies owned by the  Telephone	Fax, we (if any) : mail ad Fax, we (if any) : mail ad



Co	ompany		Activities	
	, , , , , , , , , , , , , , , , , , ,			
Are any of to other busine		f the Contractor employed	by or do they h	ave an interest
	Yes:		No	):
	er above is yes, p	please identify the individu	al, the business	and the positi
neld:				
In	dividual	Business entity	P	Position held
BUSINES	S HISTORY A	ND REFERENCES		
List any oth this question of the Contr	er agreements the, "Contractor" actor has an into	IND REFERENCES  The Contractor has with Esalulus also includes all legal entition erest) and any related entitions.	es in which the	Contractor or a
List any oth this question of the Contr	er agreements the agreements of a "Contractor" actor has an integral of affiliates):	ne Contractor has with Esa also includes all legal entition erest) and any related entition	es in which the	Contractor or a company, sub
List any oth this questior of the Contr branches an	er agreements the actor has an integral distributes.  e of Es	ne Contractor has with Esa also includes all legal entiti erest) and any related entiti saote business unit	es in which the cies (i.e. parent	Contractor or a company, sub  Type of agreement (i
List any oth this questior of the Contr branches an Nam	er agreements the actor has an integral distributes.  e of Es	ne Contractor has with Esa also includes all legal entiti erest) and any related entit saote business	es in which the cies (i.e. parent	Contractor or a

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13. List one or more Banking/Credit References (name, address, telephone, fax, e-mail address):

	Full corporate name	Name of contact person and full	Telephone	Fax	E-mail address
p					
q					
r.					

14.	Percentage of Contractor's business which is
	or will be related to Esaote's business

15. Historical Background

(e) Number of years Contractor has been in the area of business in which you will work with Esaote or on its behalf

a	
e	

(f) Briefly describe how and when the Contractor was established, the primary areas of business activity, past or proposed changes in ownership, changes, if any, of

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	business activity, etc:		
P.	SCOPE OF WORK		
9.	Contractor Agreement? If		ousiness being contemplated in the ach registration/license and provide
10.	List, if any, all employee Contractor to work on beh		duals or entities engaged by the
	Name	Title	Citizenship
11.	Please describe the experi on behalf of Esaote:	ence and qualifications of the Co	ontractor personnel who will work
		ciculum vitae regarding each loyee related to the contractual	Principal and each manager or
12.	Are there any laws, rules, Contractor Agreement wil	regulations, or practices, in the ar I be performed, that impose a li	rea in which the services under the mitation on the services that may of compensation that may be paid
	Yes:	No:	
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### **MSG Anti-Corruption** Third Parties

	If the answer is yes, plea	se explain:	
Q.	RELATIONSHIP V	WITH PUBLIC OFFICIALS	
15.	Does any current or for interest in the Contractor		ntity have any ownership or othe
	Yes:	No	
	If the answer is yes, plea	ase identify the Public Official or t	he public entity:
16.		of the Contractor a Public Officia provide services for a public entit	al or is any Principal otherwise in y?
	Yes:	No	
	If the answer is yes, plea	ase identify the Principal and the p	osition held as Public Official:
17.	term "Family Member spouse's grandparents,	of Principal" means the Principarents, siblings, children, nieces,	Distributor a Public Official? (The al's spouse; the Principal's and the nephews, aunts, uncles, and first er individuals who share the same
	Yes:	No	
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18.

19.

20.

21.

If the answer is yes, please identify the office held, the name of the person holding the office, and that person's relationship to the Principal of the Contractor.				
employer and th		neld? Please indica	ate the	what is the name of the dates of severance or
Name of	Public entity	Position or ranl	k held	Date of severance or
	tor have any kind of bic Officials or public en		, differen	it from those described
•	situations as above illusterest, with respect to t			nterests or a perception or will for Esaote?
Yes	s:	No:		
	ot already mentioned a			ading any consultant or e carried out under the
Yes	s:	No:		
	lationship to the Contra			ity that you would rely entity listed may also be

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Distributors		



#### R. FURTHER RELEVANT INFORMATION

6.	Does the Contractor have written codes, procedures or policies addressing business ethics, anti-corruption compliance, entertainment or gifts for clients or for Public Officials, or related topics? If yes, please attach.
	Yes: No:
7.	In the past 5 (five) years, has the Contractor (including any associated or previously associated organization or any predecessor organization), or any present or former Principal been (1) suspended from doing business in any capacity, (2) investigated for or charged with any criminal act, or (3) subject to any allegation of fraud, misrepresentation, bribery, corruption, tax evasion or other related activities?
	Yes: No:
	If the answer is yes, please provide complete details (on a separate sheet, if necessary):
8.	Indicate the bank, branch, city and country to which the Contractor would like compensation under the Contractor Agreement wire transferred. (Wire transfers will be made in the Contractor's name, to a bank in the Contractor's home country or in the country in which the contractual activity will be carried out).
9.	Please use this space to provide any additional information which you feel may be relevant to the relationship between the Contractor and Esaote.

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Distributors		



\* \* \*

Esaote will process personal data received by the Contractor pursuant to European Regulation 679/2016 – GDPR on personal data processing. I have reviewed this questionnaire, and I declare that the information provided is accurate and complete to the best of my knowledge and belief.

Name of the Distributor	Signature:
Date:	Typed name and title:

Please ensure the following documents are attached (and provide English/Italian translations of documents in other languages):

	Document:	Check if Attached:
<b>A.</b>	Copy of company's search, incorporating document or other evidence of establishment or incorporation of the Contractor	1
В.	Copy of required registrations or other documentation authorizing the Contractor to carry on the appropriate business, if required by local law	<b>↑</b>
C.	Independent confirmation of ownership documentation	1
D.	Curriculum vitae of each Principals and of each managers or executive or key employees related to the Contractor Agreement activity	1
Е.	Financial statements (audited, if available) for the prior three years, including balance sheets and profit and loss statements. If you cannot provide financial statements, please attach an explanation of why financial statements are not available	1
F.	Criminal records: check criminal records for the Distributor and related entities (parent companies, subsidiaries, branches and affiliates) Principals and key management personnel or individual (if legally permissible in the country concerned)	<b>↑</b>

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G.	<b>Anti-Corruption measures:</b> procedures or policies addressing business ethics, anti-corruption compliance, entertainment or gifts for clients or Public Officials.	1

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#### ATTACHMENT F – FORM OF ANTI-CORRUPTION LETTER

[Third Party's Letterhead]

[Date]

[Esaote S.p.A. or Esaote S.p.A.'s Subsidiary Contact Name Title Address]

Re: Anti-Corruption Laws

Dear:

Further to your request we confirm that our company, its officers, directors, employees, managers, and consultants conduct business with loyalty, fairness, transparency, honesty and in compliance with the applicable anti-corruption laws (such as, as the case may be, the Italian Criminal Code, the Italian Legislative Decree No. 231 of 2001, the US Foreign Corrupt Practices Act, other public and commercial anti-bribery laws in effect around the world, and international anti-corruption treaties such as the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions, and the United Nations Convention against Corruption).

We also confirm that we have implemented an effective and appropriate internal control system and a compliance program for the prevention of corruption, money laundering and other crimes.

We represent, declare as follows, also on behalf of our officers, directors, managers, consultants, and employees:

- (a) none of our officers, directors, nor the company itself, nor in any case, its managers, its employees, or its consultants are Public Officials related, directly or indirectly, to the contractual activity to be carried out or to our corporate scope;
- (b) none of our owners, shareholders or effective beneficiaries are Public Officials related, directly or indirectly, to the contractual activity to be carried out or to our corporate scope;

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(c) we will inform [Esaote/Subsidiary] promptly: (i) if any of our owners, shareholders, effective beneficiaries, officers, directors, managers, employees, consultants are appointed as Public Officials after entering into the Agreement; (ii) of any event that could influence the circumstances pertaining to the position of our owners, shareholders, effective beneficiaries, directors, managers, employees, consultants, as represented to [Esaote/Subsidiary] at the conclusion of the Agreement.

In case we will be selected and approved as [please insert the object of the Agreement].

- (a) acknowledge the contents of and commit to comply with the relevant provisions of the Organizational, Management and Control Model adopted by Esaote S.p.A./Subsidiary according to the applicable legislation, the Esaote Code of Conduct, the Esaote Management System Guideline Anti-Corruption and the Esaote Procedure on Intermediaries;
- (b) accept to draft the Agreement including in it the anti-bribery representations, warranties and commitments.

[name and title of person signin	S	Sincerely,
name and title of person signing		
	[	name and title of person signin



#### ATTACHMENT G – FORM OF INTERMEDIARY AGREEMENT

This Intermediary Agreement (hereinafter referred to as the "**Agreement**") has been stipulated on [•] in [•] [Specify date and place]

by and between:

A. [●], with registered offices in [●] (hereinafter referred to as the "Contractor"), represented by [●]

and

B. [specify the name of the Intermediary when it is an individual or his/her legal representative and the deed giving signatory powers], [residing]/[with registered offices] in [●] (hereinafter referred to as the "Intermediary"), represented by [●]

jointly referred to as the Parties, or individually as the Party.

#### 1. Subject of the Agreement

The subject of this Agreement is the appointment by the Contractor of the Intermediary for the execution by the Intermediary of the services specified herein, related to the possible award to the Contractor of the Contract (hereinafter referred to as the "Contract") and execution thereof concerning the "[ $\bullet$ ]" (hereinafter referred to as the "Project") to be performed in [ $\bullet$ ] for [ $\bullet$ ] (hereinafter referred to as the "Client").

The Intermediary shall render any service to facilitate conclusion of the Contract for the Project which is the purpose of the appointment and commits himself in particular:

- to provide the Contractor with up-to-date status reports on the development of the Project;
- to provide the Contractor with information and data suitable for the Contractor to prepare commercial and technical bids and revisions thereof;
- to give advice to the Contractor for the shaping of the best strategy to be followed towards the Client, supporting Contractor's commercial action for the Contract concerning the Project;

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- to be present on the spot or within easy reach during the negotiations for the Project, in order to keep the Contractor up-dated and duly informed on the progress of such negotiations;
- to provide the Contractor with advice and assistance in the solution of important problems that might arise during the performance of the Contract vis-à-vis the Client, such as payment of invoices, settlement of claims, etc.

all in observance of the provisions set forth in Articles 5, 6, 7 and 8.

#### 2. Definitions

Anti-Corruption Laws – means anti-corruption laws such as the Italian Criminal Code, the Italian Legislative Decree June 8, No. 231 and/or other applicable provisions, other public and commercial anti-bribery laws in effect around the world, international anti-corruption treaties such as the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions, and the United Nations Convention against Corruption.

Code of Conduct – means Esaote's Code of Conduct [attached hereto under Attachment [1]].

Contract Manager – means the Esaote's manager in charge of the management of the Agreement.

**Procedure on Intermediaries** – means Esaote's Procedure on Intermediaries [attached hereto under Attachment [3]].

Family Member – means the Public Official's spouse; the Public Official's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; the spouse of any of these people; and any other individuals who share the same household; and the private party's spouse; the private party's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; the spouse of any of these people; and any other individuals who share the same household.

**Management System Guideline Anti-Corruption** – means Esaote's Management System Guideline Anti-Corruption [attached hereto under Attachment [4]].

**Model** – means the Organizational, Management and Control Model adopted by  $[\bullet]$  (the relevant Esaote entity)

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**Principal** – means each owner (partner or shareholder) of the Intermediary, each member of the board of directors of the Intermediary, each officer or managing director of the Intermediary, each individual who is a beneficial owner of the Intermediary, each individual who is able to exercise control over the Intermediary through any arrangement, and each individual (employees and consultants) working for the Intermediary who is principally responsible for providing services in support of Contractor.

#### Public Official - means:

- (a) anyone who performs public functions in the legislative, judicial or administrative sectors;
- (b) anyone acting in an official capacity for or on behalf of (i) a national, regional or local government, (ii) an agency, department or instrumentality of the European Union or of an Italian or a non-Italian national, regional or local government (iii) an Italian or a non-Italian government-owned or government-controlled or government-participated company, (iv) a public international organization such as the European Bank for Reconstruction and Development, the International Bank for Reconstruction and Development, the International Monetary Fund, the World Bank, the United Nations or the World Trade Organization, (v) an Italian or a non-Italian political party, member of a political party, official or candidate for political office;
- (c) anyone in charge of a public service, i.e. whoever performs a public service for whatever reason, public service meaning an activity that is governed in the same way as a public function, although the power vested in the latter is absent, and the performance of simple ordinary tasks and exclusively manual work is excluded.

**Subsidiary** – means any entity directly or indirectly controlled (according to International Accounting Standards - IAS 27 "Consolidated and Separate Financial Statements", as amended from time to time) by Esaote S.p.A. in Italy and abroad.

#### 3. Efficacy and Term

- 3.1 This Agreement shall become effective upon signature thereof by both Parties and shall be considered to have automatically expired upon the occurrence of any of the following events:
  - (a) in the event that the Client has abandoned the Project or has issued a re-bid therefore; or
  - (b) in the event that the Client has signed the Contract/s for the Project with others; or

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(c) in the event that on [●], the Contract for the Project has not come into force and no renewal of this Agreement has been agreed in writing with the consent of both Parties hereto.

Tacit renewal of this Agreement is not allowed.

- 3.2 In the event that the Client awards the Contract for the Project to the Contractor and such Contract comes into force within the time limit specified in Article 3.1(c) above, or within such time limit as may be specified in any written renewal of this Agreement, then this Agreement shall be considered as terminated only upon the fulfillment of the Contractor's and the Intermediary's obligations hereunder.
- 3.3 The provisions of Articles 6 and 11 shall survive the expiry or termination of the present Agreement and shall remain applicable and enforceable by the concerned Party hereunder.

#### 4. Compensation

- 4.1 In the event that the Client will award a Contract for the Project to the Contractor and said Contract becomes effective, but only after and subject to such events, the Intermediary will be entitled to receive a percentage compensation of [●] % ([●] percent).
  - The above percentage shall be applied on the Contractor's part of the Contract price (the "Contract Price") (Client assigned items excluded), as eventually modified due to change orders/variations (insurance claims excluded) ordered by the Client under the Contract, after deduction of any local tax or withholding tax, if imposed or withheld by the Client.
  - The above compensation includes any and all taxes of whatever kind payable in [●] or anywhere else by the Intermediary as a result of the implementation of the present Agreement.
- 4.2 The above percentage compensation shall not apply on any amount, such as, but not limited to, escalation, interest on delayed payments, day-work rates, reimbursable costs, provisional sums, etc., other than the Contract Price as defined under Article 4.1 here above.
- 4.3 No compensation shall be payable to the Intermediary by the Contractor if the Contract for the Project is not signed with the Client or, even if it has been signed, it does not become effective. All and any costs sustained by the Intermediary, such as, but not limited to, travelling expenses, living and lodging expenses, office and personnel, secretarial services, telex, fax, telephone, mailing, etc., shall be at Intermediary's charge, either in case of award or of non-award of the Contract to the Contractor.

#### 5. Contract Manager and Terms of Payment

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- 5.1 The Contract Manager is [•] [specify his/her organizational unit].
- 5.2 Any payment due to the Intermediary pursuant to this Agreement shall only be made subject to the authorization in writing of the Contract Manager, who shall declare that the service has been rendered and/or confirm that the conditions foreseen in the Agreement as regards payment of the compensation have been met.
- 5.3 The compensation set forth in Article 4.1 above shall be paid to the Intermediary on [quarterly] basis, pro-rata to the amounts actually cashed by the Contractor from the Client under the Contract in the [quarter] considered. The payment of the compensation shall be subject to the verification by the Contractor of the satisfactory performance of the Intermediary's contractual obligations and shall be made to the Intermediary in the same currency of the Contract [or specify the currency], within 30 days from Contractor's receipt of regular invoices issued by the Intermediary to the Contractor.
- 5.4 The compensation shall be paid directly in favour of the Intermediary by way of bank transfer to an identified bank account in the name of the Intermediary, in a bank in [●], which shall be indicated in due course by the Intermediary. The Intermediary is strictly forbidden from requesting payment of the whole or any portion of the compensation on a bank account different from the one indicated above or in favour of another party or in another country than the home country of the Parties or other than the country where the services have to be provided.
- 5.5 The payment of the compensation under Article 4.1 will be stopped if and when the termination of the Contract will occur pursuant to Article 10, and no other amount shall be paid to the Intermediary in addition to the part of the compensation already paid or due on amounts actually and definitively cashed by the Contractor from the Client.
- 5.6 (a) In case of suspension of the works under the Contract, the payment of the compensation under Article 4.1 shall be suspended and postponed for the same period of suspension as applied in the Contract.
  - (b) In the event that it appears evident that the above suspension will lead to the termination of the Contract, the payment of the compensation set forth in Article 4.1 will be temporarily suspended up to the decision of the Client in respect of the work.
  - If the decision of the Client will be to terminate the Contract, the provisions of Article 5.5 above shall apply.

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#### 6. Representations and Warranties of the Intermediary

The Intermediary hereby represents, warrants and agrees as follows:

- (a) the Intermediary is duly organized, validly existing and in good standing under the laws of [●];
- (b) the Intermediary has all the necessary powers, licences, certifications, permissions, registrations, authorizations, to conduct its business as now conducted, to execute and deliver this Agreement and to perform the services under this Agreement;
- (c) the execution and delivery of this Agreement and the performance of the obligations under this Agreement do not and will not violate any provision of law, or any order, judgment or decree of any court or other governmental or regulatory authority;
- (d) no consent, approval or authorization of, or filing, registration or qualification with, any governmental authority on the part of the Intermediary is required as a condition to the performance of this Agreement;
- (e) the compensation and any portion thereof shall solely be used as payment for the Intermediary professional services under this Agreement;
- (f) in no case the compensation or any portion thereof shall ever be used to bribe, directly or indirectly, a Public Official or any of its Family Members;
- (g) in no case the compensation or any portion thereof will be paid or redirected, directly or indirectly, to partners, shareholders, or members of the corporate bodies of the Client in violation of the applicable laws;
- (h) in no case the compensation or any portion thereof will be paid or redirected, directly or indirectly, to members of the corporate bodies, directors or employees of Contractor or, of other companies belonging to Contractor Group and/or to any of their Family Members;
- (i) neither the Intermediary, nor its Family Members, [nor, (when the Intermediary is a company), any of its Principals] are Public Officials;
- (j) the Intermediary knows and commits to comply with applicable laws, Anti-Corruption Laws, the Management System Guideline Anti-Corruption, the Procedure on Intermediaries, the relevant provisions of the Model and the Code of Conduct;

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- (k) the Intermediary has received copies of and the relevant information on the Code of Conduct, the Model, the Management System Guideline Anti-Corruption and the Procedure on Intermediaries which are attached hereto, respectively, as Attachment [1, 2, 4 and 3], and considered an integral part hereof;
- (l) the Intermediary has implemented an effective and appropriate internal control system and a compliance program for the prevention of corruption, money laundering and other crimes, that the Intermediary will keep in place for the entire duration of this Agreement;
- (m) [only in case of multiyear contracts] the Intermediary will confirm the representations and commitments as set forth in the foregoing points and submit a specific written statement upon each annual expiry of the Agreement or at the request of the Contractor.

#### 7. Obligations and duties on the Intermediary –Rights of the Contractor

- 7.1 The Intermediary agrees and undertakes:
- (a) in performing the assignment under this Agreement to act with diligence, correctness, honesty, integrity and transparency;
- (b) not to behave or act in a way that may reflect negatively upon Contractor's business integrity, image or goodwill;
- (c) to act [and, in case of a company, to cause all of its Principles to act] in compliance with all applicable laws, the Anti-Corruption Laws, the Code of Conduct, the relevant provisions of the Model, the Management System Guideline Anti-Corruption and the Procedure on Intermediaries;
- (d) not to take on commitments or obligations in the name and/or on behalf of Contractor or a company belonging to Contractor Group, and not to use the name of Contractor or a company belonging to Contractor Group and not to introduce himself to third parties as a representative, agent or employee of Contractor or a company belonging to Contractor Group;
- (e) to inform Contractor promptly in case he/she, one of his/her Family Members [(when it is a company) or any of its Principals] will be appointed as Public Officials during the performance of this Agreement;

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- (f) to inform Contractor promptly of any event that is likely to affect the circumstances pertaining to the Intermediary's position or that of his/her Family Members, [(when it is a company) or of its Principals] declared to Contractor upon conclusion of this Agreement;
- (g) not to assign, cede or transfer this Agreement to third parties and not to cede, assign, delegate or sub- contract all or any part of the obligations or rights created under this Agreement without the prior authorization in writing from Contractor;
- (h) [only in case of multiyear contracts] that the Intermediary will reaffirm and confirm the statements and commitments as set forth in the foregoing points by submitting a specific written statement upon the annual expiry of this Agreement or at the request of Contractor;
- (i) not to assist any other competitor of the Contractor during the validity of this Agreement;
- (j) to keep adequate personnel in order to ensure the most convenient support and assistance to the Contractor at all times.

#### 7.2 The Contractor shall have the right:

- (a) to appoint also other intermediary/ies, agent/s, consultant/s and or adviser/s for the Project and to avail itself of their services, it being understood that in case of awarding of the Contract for the Project to the Contractor thanks to the services supplied by the Intermediary, the Intermediary shall be entitled to receive the compensation as per Article 4.1 herein before;
- (b) to decide whether to submit or not the offer for the Project or revisions thereof, to keep or withdraw the offer already submitted, to accept or to refuse the award of the Contract, all this at the Contractor's sole discretion. Any of the above Contractor's decisions terminating Contractor's participation in the Project will not entitle the Intermediary to any right or expectation whatsoever in respect of any compensation or expense under Article 4.1 and Article 4.3 herein and this Agreement shall be thereupon terminated;
- (c) to assign the present Agreement to a company belonging to Contractor's Group;
- (d) to disclose the contents of this Agreement to other persons within Contractor's Group or in case of mandatory disclosure.

#### 8. Administrative Responsibility

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The Intermediary declares to have knowledge of the legislation in force regarding the administrative liability of the legal entities. In this connection the Intermediary declares to have received and have knowledge of the contents of document "Model" drafted by Contractor.

The Intermediary declares to have adopted and effectively implemented all [its own] company's internal procedures and policies and to have duly instructed its employees and/or agents in order to prevent the commission or attempt of any offence under applicable Anti-Corruption Laws.

The Intermediary undertakes vis-à-vis the Contractor to maintain such procedures, policies and instructions effectively implemented for the entire duration of this Agreement.

The Parties agree that non-compliance, even partial, with the adoption and/or implementation and/or continuation of the above procedures, policies, and instructions will be considered a material default under this Agreement justifying its immediate termination. As a consequence, Contractor shall have the right to:

- (a) suspend its performance of this Agreement by delivering notice via registered mail, which shall include a brief summary of the information, including news from the press, concerning the circumstances or the legal proceedings upon which it is reasonable to infer the non-compliance, and/or, in any event,
- (b) unilaterally withdraw from the Agreement, even during its performance, or terminate this Agreement with automatic and immediate effect, by delivering notice via a registered mail, which shall include a brief summary of the circumstances or legal proceedings demonstrating such non-compliance.

The exercise of the rights under (a) and (b) above will be to the sole detriment of the Intermediary and the Intermediary shall bear all additional expenses and costs arising from or consequential to the exercise of these rights, without prejudice to Contractor's right to claim all economic or non-economic damages arising from the default/non-compliance as set forth above. In addition, the Intermediary has exclusive liability for any event or adverse consequence or damage of any nature that may arise from the non-compliance, as well as the obligation to hold Contractor harmless from any third-party action arising from or consequential to such non-compliance.

#### 9. Controls

Contractor retains the right to make controls, including audit and accounting controls, at the Intermediary's, [in the event that Contractor has a reasonable belief that the Intermediary has violated the Anti-Corruption Laws or any of the obligations or representations under article 6 and 7]. The

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Intermediary shall provide the documentation and information reasonably requested for the purpose of making said controls.

The Intermediary is to retain documents for business performed on Contractor's behalf in electronic or paper format for a minimum of [10] years. Thereafter the Intermediary may destroy documents unless prevented from doing so by local regulation and provided always that the Intermediary proposing to destroy documents first obtains the Contractor's written consent, which consent is not to be unreasonably withheld.

Contractor retains the right to disclose the contents and information learned during the performance hereof, and said controls to other parties belonging to Contractor, and to third parties when a legitimate request is made. The Intermediary shall provide the information to said third parties at Contractor's request.

#### 10. Events of Default and Termination

Without prejudice to the provisions set forth in Article 8, Contractor retains the right to terminate this Agreement at any time by providing seven days' written notice, in the following cases:

- (a) failure by the Intermediary to duly perform or observe any term, provision, covenant, agreement or condition on its part to be performed or observed under this Agreement;
- (b) breach of the anti-corruption obligations, any breach, untruth or inaccuracy in any representation and warranty as set forth in Articles 6, 7 and/or in the event of violation of the Anti-Corruption Laws, the Code of Conduct, the relevant provisions of the Model, the Management System Guideline Anti-Corruption or the Procedure on Intermediaries;
- (c) [in the event a bankruptcy petition is filed by the Intermediary or the same is admitted to other insolvency proceedings, or is put in voluntary or compulsory liquidation.]; and
- (d) upon change of control of the Intermediary.

Upon termination of the Agreement the Intermediary will have no right to payment of the compensation, which shall be withheld by Contractor as penalty, when the compensation has not been paid in full or only a portion has been paid.

#### 11. Indemnification

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The Intermediary shall indemnify and agree fully to defend, save and hold [Contractor and other entities of the Contractor Group] harmless, if [Contractor and/or other entities of the Contractor Group] at any time or from time to time suffer any damage, liability, obligation, loss, cost, expense (including all reasonable attorneys', consultants' and experts' fees, including such fees incurred in any action or proceeding between [Contractor and/or other entities of the Contractor Group], on the one hand, and the Intermediary, on the other hand), claim or cause of action against [Contractor and/or other entities of the Contractor Group], or any of their respective officers, directors, managers, employees, shareholders, partners, members and representatives, as applicable, arising out of, relating to or resulting from – or pay or become obligated to pay any sum on account of – any and all events of default as described in Articles 8 and 10. In no circumstance would the damages be less than the compensation that would be payable plus the interest which would accrue.

#### 12. Expenses

[The Intermediary shall be entitled to obtain reimbursement of travelling and board expenses incurred while carrying out the assignment, which have been approved in writing beforehand by Contractor and provided that they are reasonable and are supported by adequate expense voucher.]

#### 13. General Rules

For the entire term of this Agreement and after the termination hereof for any reason, the Intermediary shall not use any confidential, technical or commercial information concerning the production processes, or business and commercial strategies of Contractor, or any information the Intermediary has learned, obtained or received whilst performing its obligations as set forth herein, or as a direct or indirect consequence of the performance of obligations which exceed the scope of those set forth herein, and further agrees not to disclose or communicate them to third parties. The Parties agree that this provision shall cease to be applicable in the event the information is made public in a manner other than due to a breach of this Agreement.

No provisions contained in this Agreement may be intended or construed as to form an association between the Parties, or to appoint the Intermediary as agent, employee or representative of Contractor for any purpose. In acting under this Agreement, the Intermediary will not assume any obligations towards or relationship of agency or trust for Contractor and shall have no authority or power to take on commitments for Contractor or to establish guarantees on the assets or credits of the same.

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Any communication, informative brief or notification required or consented to by the terms hereof must be in writing [in the [•] language] and be sent by registered mail, return receipt requested, or by telex or facsimile or other means of written communication (to be confirmed by telephone or email at the address of the recipient). Any such communications shall take effect, if delivered in person, upon receipt or, in the case of a telex or facsimile, 24 hours after the time of despatch.

Communications relevant to this Agreement shall be sent in writing to the following addresses:

to the Contractor:

attention: [specify the manager's name] address:  $[\bullet]$  fax  $[\bullet]$ 

to the Intermediary:
attention: [specify the manager's name]
address: [●]
fax [●]

This Agreement is stipulated in the [•] language. The Parties hereby agree that if it is necessary to translate this Agreement into the [•] language, the [•] version shall prevail and shall be considered decisive for the interpretation of the scope and intent of each article hereof.

No failure to exercise, nor any delay in exercising, any right or remedy by Contractor under this Agreement shall operate as a waiver of that right or remedy, nor shall any single or partial exercise of any right or remedy prevent any further or other exercise of that right or remedy or the exercise of any other right or remedy under this Agreement.

If any one or more of the covenants, agreements, provisions or terms of this Agreement are held invalid for any reason whatsoever, then such covenants, agreements, provisions or terms shall be deemed severable from the remaining covenants, agreements, provisions or terms of this Agreement and shall in no way affect the validity or enforceability of the other provisions of this Agreement unless such severance would materially alter the intentions of the Parties as set forth in this Agreement.

This Agreement constitutes the entire agreement between the Parties hereto in connection with the Project and replaces and supersedes all prior agreements, either written or oral, negotiations, correspondence and the like concerning the subject matter hereof.

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No alterations and/or amendments will be made to this Agreement except by agreement in writing between the Parties hereto.

#### 14. Governing Law and Settlement of Disputes

This Agreement shall be interpreted and the rights of the Parties determined in accordance with [•]. In case of any dispute between the Parties relating to or arising out of the interpretation, performance or termination of this Agreement, each Party will use its best efforts in order to settle such dispute in a friendly manner.

If the Parties cannot come to an understanding, the dispute shall be finally settled [under the Rules of Arbitration of [•] by [three] arbitrators appointed in accordance with such Rules.

The place of arbitration will be [•] and arbitration proceedings will be conducted in the [•] language. The award of the arbitrators or of two of them in writing shall be final and binding upon the Parties and shall not be appealed or contested in any court, and if either Party fails to abide by such award and the other Party seeks an order of a court for its enforcement, the Party so failing to abide shall be responsible for the payment of any resulting enforcement expenses and tax burdens, including registration taxes.]

#### **Attachments**

- 1) Code of Conduct;
- 2) Model;
- 3) Procedure on Intermediaries;
- 4) Management System Guideline Anti-Corruption.



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#### 1 SCOPE AND PURPOSE

This Procedure on Standard Contractual Clauses to apply with Business Partners (the "**Procedure**") is part of the Esaote Procedures finalized to prevent bribery-related risks, provided for under the Management System Guideline Anti-Corruption.

The purpose of this Procedure is to define the criteria and responsibilities for the standardization of contractual clauses regarding the administrative responsibility of legal entities arising from criminal offenses in compliance with Esaote's 231 Model.

#### 2 REFERENCE

- Code of Conduct;
- Model;
- "Management System Guideline Anti-Corruption";
- Procedure on Third Parties;
- Procedure on Joint Venture Agreements.

#### 3 DEFINITIONS

When used in this Procedure, the following terms have the meanings set forth below:

**ANTI-CORRUPTION LAWS**: the Italian Criminal Code, the Legislative Decree 231 and other applicable provisions, the FCPA, the UK Bribery Act, other public and commercial anti-bribery laws in effect around the world, and international anti-corruption treaties such as the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions, and the United Nations Convention against Corruption.

**CODE OF CONDUCT**: Esaote's Code of Conduct.

**COMPLIANCE OFFICER**: A resource within the Company entrusted with the management and implementation of policies aimed at avoiding or reducing the exposure to liability for any violation of national or international regulations, decisions of competent authorities or other applicable rules of conduct. The Esaote Compliance Officer: (i) ensures knowledge of applicable regulations; (ii) makes proposals, preparation and update of compliance policies for preventing any corporate conduct that may be contrary to regulations; (iii) acts as reference person for Group companies; (iii) reports on the implementation and monitoring of compliance policies to the Board of Directors; (iv) assists the 231 Supervisory Body in relation to any Legislative Decree 231 issue; and (v) carries out communication and training on compliance policies.

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**ESAOTE**: Esaote S.p.A. and its Subsidiaries.

**ESAOTE ANTI-CORRUPTION REGULATIONS**: Esaote MSG and Esaote Procedures finalized to prevent bribery-related risks.

It is responsibility of each single process owner of the relevant MSG to update the regulations (or to issue new regulations) concerning the subjects listed above, also to ensure compliance with this MSG. In defining such regulations, the Esaote Compliance Officer must be consulted.

**ESAOTE PERSONNEL**: the directors, officers, members of corporate bodies, managers and employees of Esaote.

**INTERMEDIARY**: an independent individual or a company that Esaote proposes to retain to: (i) promote the commercial interests of Esaote and/or any of its Subsidiaries in relation to a single transaction/project; (ii) facilitate the stipulation and/or execution of contracts with third parties; and/or (iii) put in contact/introduce Esaote S.p.A. and/or any of its Subsidiaries to one or more other parties for the purpose of bringing/generating or retaining a business.

**INTERNAL AUDIT:** If appointed, a professional or a company appointed by Esaote S.p.A. responsible for the examination and independent evaluation of the internal control system, in order to verify the compliance with the requirements of the Management System Guideline Anti-Corruption, on the basis of its periodical audit plan approved by the Board of Directors of Esaote S.p.A. based on the preliminary opinion of the Audit and Compliance Committee.

**LEGISLATIVE DECREE 231**: Italian Legislative Decree June 8, 2001, No. 231, as amended from time to time.

**MANAGEMENT SYSTEM GUIDELINE ANTI-CORRUPTION:** Esaote's Management System Guideline Anti-Corruption approved by the Board of Directors of Esaote S.p.A..

**MANAGER**: The most senior manager of the department, of the area or of the operative company requiring the services subject matter of the agreement.

**MODEL 231**: the Model concerning the organization, management and controlling activities of Esaote (ex Legislative Decree 231 of 2001) approved by the Board of Directors of Esaote S.p.A..

#### **PUBLIC OFFICIAL:**

(a) anyone who performs public functions in a legislative, judicial or administrative capacity;

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- (b) anyone acting in an official capacity for or on behalf of (i) a national, regional or local government, (ii) an agency, department or instrumentality of the European Union or of an Italian or a non-Italian national, regional or local government, (iii) an Italian or a non-Italian government-owned or government-controlled or government-participated company, (iv) a public international organization such as the European Bank for Reconstruction and Development, the International Bank for Reconstruction and Development, the International Monetary Fund, the World Bank, the United Nations or the World Trade Organization, or (v) an Italian or a non-Italian political party, member of a political party, official or candidate for political office;
- (c) anyone in charge of providing a public service, i.e. whoever performs a public service for whatever reason, where public service means an activity that is governed in the same way as a public function, except that the power vested in the latter is absent. The performance of basic ordinary tasks and exclusively manual work is excluded.

**SUBSIDIARY**: any entity that is directly or indirectly controlled by Esaote S.p.A.(1) in Italy and abroad.

**231 SUPERVISORY BODY:** the supervisory body (*Organismo di Vigilanza*) of Esaote S.p.A., as defined in Esaote Organizational Model and appointed pursuant to the Legislative Decree 231.

#### 4 PROCEDURES AND RESPONSIBILITIES

Each Esaote Function is required to introduce in the agreements with agents, consultants, employees, business partners and joint ventures involving activities covered by Model 231, in whole or in part depending on the activity regulated by the agreement, a special "Administrative Responsibility" clause, whose content is compliant with this procedure

By letter motivated, any Manager can submit to the Esaote Compliance Officer a request aimed at not including the "Administrative Responsibility" clause in a specific agreement.

All the Subsidiaries that enter into contracts, if they have not adopted a Model of Organisation, Management and Control, must conform to the principles contained in the Model 231, Code of Conduct and Esaote Anti-Corruption Regulations and to ensure that their work complies with the principles set forth therein.

#### 4.1 Clause "Administrative Responsibility" for "Clients, Customers or Buyer"

(1) The list of these companies is that included in the appendix "Controlled subsidiaries" of the most recent approved consolidated financial statement.

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With reference to the performance of activities under this Agreement, the "client\customer\buyer" declares to have read and be familiar with the contents of the Model 231, Code of Conduct and of the relevant Esaote Anti-Corruption Regulations. The "client\customer\buyer" will, at all times, the right to request to Esaote delivery of a copy of the mentioned documentation. Model 231 and Code of Conduct are also available on the site <a href="https://www.esaote.it">www.esaote.it</a>.

#### 4.2 Clause "Administrative Responsibility" for "Contractors"

The Contractor declares to have knowledge of the legislation in force regarding the administrative liability of the legal entities. In this connection the Contractor declares to have received and have knowledge of the contents of document "Model" drafted by Esaote/Esaote's Subsidiary.

The Contractor declares to have adopted and effectively implemented all [its own] company's internal procedures and policies and to have duly instructed its employees and/or agents in order to prevent the commission or attempt of any offence under applicable Anti-Corruption Laws.

The Contractor undertakes vis-à-vis Esaote/Esaote's Subsidiary to maintain such procedures, policies and instructions effectively implemented for the entire duration of this Agreement.

The Parties agree that non-compliance, even partial, with the adoption and/or implementation and/or continuation of the above procedures, policies, and instructions will be considered a material default under this Agreement justifying its immediate termination. As a consequence, Esaote/Esaote's Subsidiary shall have the right to:

- (a) suspend its performance of this Agreement by delivering notice via registered mail, which shall include a brief summary of the information, including news from the press, concerning the circumstances or the legal proceedings upon which it is reasonable to infer the non-compliance, and/or, in any event,
- (b) unilaterally withdraw from the Agreement, even during its performance, or terminate this Agreement with automatic and immediate effect, by delivering notice via a registered mail, which shall include a brief summary of the circumstances or legal proceedings demonstrating such non-compliance.

The exercise of the rights under (a) and (b) above will be to the sole detriment of the Contractor and the Contractor shall bear all additional expenses and costs arising from or consequential to the exercise of these rights, without prejudice to Esaote's/Esaote's Subsidiary's right to claim all economic or non-economic damages arising from the default/non-compliance as set forth above. In addition, the Contractor has exclusive liability for any event or adverse consequence or damage of any nature that may arise from the non-compliance, as well as the obligation to hold Esaote/Esaote's Subsidiary harmless from any third-party action arising from or consequential to such non-compliance.

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#### 4.3 Clause "Administrative Responsibility" for "Intermediaries"

The Intermediary declares to have knowledge of the legislation in force regarding the administrative liability of the legal entities. In this connection the Intermediary declares to have received and have knowledge of the contents of document "Model" drafted by Contractor.

The Intermediary declares to have adopted and effectively implemented all [its own] company's internal procedures and policies and to have duly instructed its employees and/or agents in order to prevent the commission or attempt of any offence under applicable Anti-Corruption Laws.

The Intermediary undertakes vis-à-vis the Contractor to maintain such procedures, policies and instructions effectively implemented for the entire duration of this Agreement.

The Parties agree that non-compliance, even partial, with the adoption and/or implementation and/or continuation of the above procedures, policies, and instructions will be considered a material default under this Agreement justifying its immediate termination. As a consequence, Contractor shall have the right to:

- (a) suspend its performance of this Agreement by delivering notice via registered mail, which shall include a brief summary of the information, including news from the press, concerning the circumstances or the legal proceedings upon which it is reasonable to infer the non-compliance, and/or, in any event,
- (b) unilaterally withdraw from the Agreement, even during its performance, or terminate this Agreement with automatic and immediate effect, by delivering notice via a registered mail, which shall include a brief summary of the circumstances or legal proceedings demonstrating such non-compliance.

The exercise of the rights under (a) and (b) above will be to the sole detriment of the Intermediary and the Intermediary shall bear all additional expenses and costs arising from or consequential to the exercise of these rights, without prejudice to Contractor's right to claim all economic or non-economic damages arising from the default/non-compliance as set forth above. In addition, the Intermediary has exclusive liability for any event or adverse consequence or damage of any nature that may arise from the non-compliance, as well as the obligation to hold Contractor harmless from any third-party action arising from or consequential to such non-compliance.

#### 4.4 Clause "Administrative Responsibility" for other "Business Partners"

**INSTRUCTIONS**: the standard clauses specified below are applicable in any joint venture agreements, consortium, shareholder agreements or other partnership agreements (including ATI - "Associazione Temporanea di Imprese").

In particular:

• <u>Clause A</u> is applicable when the joint venture, consortium, partnership is an <u>incorporated</u> legal entity autonomous from Esaote and its Partners;

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• <u>Clause B</u> is applicable when Esaote and its Partners agree to not set up an autonomous legal entity (e.g., unincorporated joint ventures, ATI - "Associazione Temporanea di Imprese")

Regarding Clause A, in the event the legal entity is under the direct or indirect control of Esaote, the section of the agreements of joint venture/consortium/shareholder agreement/partnership in relation to "default/remedies" must expressly provide that a breach of the clause in question to determine the non-defaulting party, the right to termination of agreements or arrangements similar output from the partnership of Esaote or non-defaulting party [or the right to the exclusion of the defaulting party]. In the other cases (*i.e.* when the legal entity incorporated by Esaote and its Partners is not under the exclusive control of Esaote), the provisions of Clause A should be a reference in its negotiation of partnership agreements, taking into account the specific situations of fact, partners, or significant events of the previous reports, the local context in which the legal entity will work, with the aim of obtain a detailed contract as much as possible adhering to the standard clause specified below and in any case by agreeing, in the event of default, remedies in analogy to what is reported in the previous paragraph.

NOTE: the adoption of the terms which do not incorporate, or modify the clauses indicated below requires the prior evaluation of the Esaote Compliance Officer

#### CLAUSE A

Each Party undertakes to comply with the provisions of applicable anti-corruption laws, and claims to have received and have knowledge of other Parties' anti-corruption regulations.

The Parties agree as follows:

- (a) the Parties shall comply in relation to their performance under this Agreement, and shall use all reasonable endeavors to ensure that [legal entity] complies, with the provisions of the applicable anti-corruption laws and the principles of each Party's anti-corruption regulations and abstain from, directly or indirectly, offering, promising, giving, paying or accepting any public official's request for a gift, or authorizing anyone to give or pay, directly or indirectly, any sums, other benefits or advantages or anything of value to or for a public official or their family members, shareholders, partners or members of the governing bodies of the counterparty with which the [legal entity] intends to operate.
- (b) The Parties shall use all reasonable endeavors to ensure that [legal entity] adopts and puts in place an effective and appropriate internal control system and a "Compliance Program" for the prevention of corruption, money laundering and other crimes, in accordance with the anti-corruption laws and adopt internal procedures, consistent with each party's anti-corruption regulations, designed to ensure (i) compliance with the anti-corruption law by [legal entity], its employees, agents, consultants, contractors, representatives, and (ii) the employment of any agent or broker and any payment to an employee, agent, broker, consultant or contractor is

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subject to specific authorization and properly recorded in the books and records of the [legal entity].

Each Party shall have the right to verify compliance by the [legal entity] with the above requirements .

#### CLAUSE B

Each Party declares to have reviewed and have knowledge of the contents of the other Parties' anticorruption regulations.

With respect to the performance of the activities under this Contract, the Parties represent and warrant that they have given and implemented instructions to its directors, employees and/or agents, aimed at preventing any and all conducts in breach of any applicable anti-corruption law and undertake to continue effectively implementing such instructions for the entire duration of this Contract. In particular and in accordance with the abovementioned laws, the Parties undertake to abstain (and to cause their directors, employees and/or agents to abstain) from, directly or indirectly, offering, promising, giving, paying or accepting any public official's request for a gift, or authorizing anyone to give or pay, directly or indirectly, any sums, other benefits or advantages or anything of value to or for a public official or his family members, shareholders, partners or members of the governing bodies of the counterparty with which the Parties intend to operate pursuant to the Contract.

With respect to the performance of the activities under this Contract, the Parties undertake for the entire duration of this Contract to strictly abide by the provisions of applicable anti-corruption laws and the principles of each Party's anti-corruption regulations.

The Parties agree that any non-compliance, even partial, with the abovementioned representations, warranties and undertakings, which can be reasonably expected to result in adverse consequences for a Party, will be considered a material default under this Contract and will entitle such Party to unilaterally withdraw, even during its performance, or to terminate the Contract, by delivering notice via registered mail, which shall include a brief summary of the circumstances or of the legal proceedings demonstrating such non-compliance.

In the event of information that could reasonably imply such non-compliance, pending the required verifications or findings any compliant Party will have the right to suspend the performance of the Contract by delivering notice via registered mail, which shall include a brief summary of the relevant information. Should the information be obtained from the media, any compliant Party shall have the right to exercise such right when the information has been confirmed by an official document of the Judicial Authority and/or otherwise confirmed by the Judicial Authority.

The exercise of such rights will be to the sole detriment of the non-compliant Party, which shall bear, in all cases, all additional expenses and costs and shall be liable for and defend, indemnify and



hold harmless the other Parties from any third-party action arising from or consequential to such non-compliance.



# MSG Anti-Corruption Ordinary reporting and confidential reporting

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# esaote

### **MSG Anti-Corruption**

Ordinary reporting and confidential reporting

#### 1 PURPOSE

This Procedure on Ordinary reporting and confidential reporting (the "**Procedure**") is part of the Esaote Procedures finalized to prevent bribery-related risks, provided for under the Management System Guideline Anti-Corruption.

The purpose of this Procedure is to regulate the principles and rules to be followed by Esaote and its Subsidiaries in the management of the reports concerning any actual or suspected violations of the Anti-Corruption Laws, Model 231, Code of Conduct and Esaote Anti-Corruption Regulations. In particular, the purpose of this policy is to:

- Encourage Esaote Personnel, to ask questions and report any concerns it should have over any Alleged Misconduct.
- Outline the various communication channels available to Esaote Personnel to report (also anonymously) as well as the processes for resolving any Reported Matters.
- Reassure Esaote Personnel that no retaliation will be tolerated against it for reporting in Good Faith.
- Enable management to be better informed at an early stage of any Alleged Misconduct so that corrective action can be taken promptly.

#### 2 SCOPE

This policy applies to any and all Esaote activities, regardless of function, located in any and all countries. This includes full-time, part-time, contract and temporary employees.

#### 3 DEFINITIONS

When used in this Procedure, the following terms have the meanings set forth below:

**ANTI-CORRUPTION LAWS**: the Italian Criminal Code, the Legislative Decree 231/2001 on administrative responsibility of authorities (the "Decree") and other applicable provisions, the FCPA, the UK Bribery Act, other public and commercial anti-bribery laws in effect around the world, and international anti-corruption treaties such as the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions, and the United Nations Convention against Corruption.

**CODE OF CONDUCT**: Esaote's Code of Conduct.

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Ordinary reporting and confidential reporting

**MODEL 231**: the Model concerning the organization, management and controlling activities of Esaote (ex Legislative Decree 231 of 2001) approved by the Board of Directors of Esaote S.p.A.

**ESAOTE ANTI-CORRUPTION REGULATIONS**: Esaote MSG and Esaote Procedures finalized to prevent bribery-related risks.

It is responsibility of each single process owner of the relevant MSG to update the regulations (or to issue new regulations) concerning the subjects listed above, also to ensure compliance with this MSG. In defining such regulations, the Esaote Compliance Officer must be consulted.

**INTERMEDIARY**: an independent individual or a company that Esaote proposes to retain to: (i) promote the commercial interests of Esaote and/or any of its Subsidiaries in relation to a single transaction/project; (ii) facilitate the stipulation and/or execution of contracts with third parties; and/or (iii) put in contact/introduce Esaote S.p.A. and/or any of its Subsidiaries to one or more other parties for the purpose of bringing/generating or retaining a business (e.g. sales agents)

**INTERNAL AUDIT:** if appointed, a professional or a company appointed by Esaote S.p.A. responsible for the examination and independent evaluation of the internal control system, in order to verify the compliance with the requirements of this MSG, on the basis of its periodical audit plan approved by the Board of Directors of Esaote S.p.A. based on the preliminary opinion of the Compliance and Audit Committee, in the event it is appointed within the Board of Directors.

**ALLEGED MISCONDUCT**: actual or suspected misconduct or unethical business practices within Esaote or by any Third Party with whom Esaote does business and includes:

- violation of laws and regulations;
- a criminal offence;
- intentional provision of incorrect information to public bodies;
- violation of the Code of Conduct or any Esaote policies and with reference to procedures under the Model 231;
- intentional suppression, destruction or manipulation of information regarding the facts in connection with any of the above;
- circumstances that can directly or indirectly damage Esaote's reputation.

#### **GOOD FAITH**: a report made

- without malice, false accusations or consideration of personal benefit
- in presence of a reasonable basis to believe the Reported Matter is true

A Reported Matter does not need to be proven true to be made in Good Faith.

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Ordinary reporting and confidential reporting

**INVESTIGATOR**: is the person assigned to investigate a Reported Matter in accordance with this policy. It may be:

- an internal Investigator (e.g.: an the Internal Audit, if appointed or the Compliance Officer or a Esaote Personnel entrusted with such duty by Internal Audit/ Compliance Officer)
- an external Investigator (e.g.: an external consultancy firm or law firm who is experienced in handling such matters, and may include external auditors, forensic investigators, etc.)

**RECOMMENDED REPORT INFORMATION FORM:** is the form that includes the information that should be provided in a report, a copy of which is attached to this Procedure as Attachment A

**HUMAN RESOURCES DEPARTMENT:** The human resources department of Esaote S.p.A.

**REPORTED MATTER**: is any matter that is reported through the various communication channels in accordance with this Procedure.

**231 SUPERVISORY BODY:** the supervisory body (*Organismo di Vigilanza*) of Esaote S.p.A., as defined in Esaote Organizational Model and appointed pursuant to the Legislative Decree 231.

#### 4 GENERAL GUIDING PRINCIPLES

The Basic Principles

- This Procedure covers asking questions and reporting concerns Esaote Personnel have over Alleged Misconduct, including anonymously.
  - This Procedure should be viewed as a constructive process to resolve issues around Alleged Misconduct in an effective and timely manner. It is not intended to cover work related issues, employee grievances or complaints that should primarily be handled by any Manager or by Human Resources Department
- Esaote Personnel have a responsibility to report in Good Faith using the various communication channels.
  - Esaote Personnel responsibility is to ask questions or report matters about Alleged Misconduct. Esaote Personnel should not attempt to investigate or resolve a Reported Matter on its own. Any Manager who receives a report of Alleged Misconduct must take action to resolve the issues after having communicated it to the Compliance Officer and following the instructions received. Anyone who knowingly or recklessly reports without Good Faith may be subject to disciplinary action.

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Ordinary reporting and confidential reporting

Reported Matters will be handled on a confidential and impartial basis. Any action taken will be conducted in a professional, objective, unbiased and sensitive manner with the aim of either substantiating or invalidating the Reported Matter, it being understood that the Company will apply all what provided for by Law 179/2917 and following amendments and integrations, thus ensuring to reporters all safeguards under said regulation and, finally, all what provided for by art. 6 of the Decree, par. 2 bis and following, stating that the retaliatory or discriminatory dismissal of the whistleblower is invalid. A change of responsibilities as defined in Article 2103 Civil Code, as well as any other retaliatory or discriminatory measure adopted against the reporting party are also invalid. It is the employer's responsibility, in case of disputes related to the imposition of disciplinary sanctions or demotions, dismissals, transfers or subjection of the whistleblower to another organizational measure having direct or indirect negative effects on their working conditions after the submission of the report, to demonstrate that these measures are based on reasons not related to the report.

- No retaliation will be tolerated against Esaote Personnel for reporting in Good Faith.
- Esaote Personnel must not communicate with any external Third Party in relation to a Reported Matter without the pre-approval of the Esaote Compliance Officer
- This Procedure covers the reporting and investigation of Alleged Misconduct as well as protection of the Esaote Personnel who report.

This Procedure complements the Model 231, the Code of Conduct and the Esaote Anti-Corruption Regulations, in particular the prevention and detection of fraud and misconduct in respect of accounting, internal controls, auditing matters and reporting and corruption, therefore ensuring the financial integrity, security and reputation of Esaote.

#### 5 SPECIFIC GUIDING PRINCIPLES OF REPORTING

These guiding principles set out how this Procedure may apply to Esaote Personnel issuing a report.

#### No Retaliation

No retaliation will be tolerated against Esaote Personnel for reporting in Good Faith. Retaliation includes dismissal, demotion, suspension, harassment or other forms of discrimination, in compliance with abovementioned principles under art. 6 of the Decree. It does not matter if the Alleged Misconduct proves to be incorrect or unsubstantiated if Esaote Personnel report in Good Faith. The Esaote Personnel that believe being retaliated against, may file a complaint in accordance with the this Procedure to Human Resources Department. All complaints of retaliation will be reviewed promptly and the issuer of the

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Ordinary reporting and confidential reporting

complaint will be informed of the outcome. Anyone who retaliates against another person will be subject to disciplinary action.

#### • <u>Confidentiality</u>

The Esaote Personnel may prefer to report in confidence, using specific reporting channels available in compliance with abovementioned principles under art. 6 of the Decree and not to be identified during an investigation. Esaote will protect the identity of who reports to the greatest extent possible and by only involving people on a "need to know" basis. If a situation arises where it is not possible to resolve a Reported Matter without revealing the identity of the person who reports, the person dealing with the Reported Matter will discuss with him/her how to proceed. For serious matters (e.g. involving potential legal proceedings) Esaote will need to have the final decision on how to proceed.

#### • <u>Anonymity</u>

The Esaote Personell may report anonymously. Esaote will investigate matters reported to the extent it is believed they could be true and possible with whatever information has been provided. Esaote will take into account the seriousness of the Alleged Misconduct raised, the credibility of the concern and the likelihood of confirming the Alleged Misconduct from attributable sources. Matters reported anonymously are obviously more difficult to investigate and resolve and therefore Esaote Personeel are encouraged to identify themself whenever possible.

#### <u>Disciplinary Action</u>

Various types of disciplinary action may apply. If any Alleged Misconduct is substantiated, appropriate disciplinary action will be taken. Anyone who retaliates against another person will be subject to disciplinary action. Anyone who knowingly or recklessly report without Good Faith may be subject to disciplinary action.

#### **6 REPORTING PROCESS**

- 1. Esaote Personnel should initially ask questions and report any concerns over any Alleged Misconduct with the relevant business unit/function Head.
- 2. If this is not possible (e.g. because the Alleged Misconduct involves management) or the relevant Esaote Personnel are more comfortable using an alternative reporting channel, the following communication channels are also available.

CHANNEL	CONTACT DETAILS	RECEIVED, REVIEWED &

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Ordinary reporting and confidential reporting

		MANAGED BY	
Supervisory Boo	Supervisory Body under D. Lgs. 231/2001		
Email	odv231@esaote.com	OdV	
Mail	Send to:	OdV	
	Esaote SpA		
	Via Enrico Melen, 77		
	16152 Genova		
	Italia		
	Att: Organismo di Vigilanza		
COMPLIANCE	E OFFICER		
Email	compliance officer@esaote.com	Compliance	
		Officer	
2.5.11			
Mail	Send to:	Compliance	
	Esaote SpA	Officer	
	Via Enrico Melen, 77		
	16152 Genova		
	Italia		
	Att: Compliance Officer di Esaote S.p.A.		

Esaote Personnel should provide as much information as possible when it reports as the more specific and relevant the information, the easier it will be for Esaote to deal with the Reported Matter.

Any Reported Matters should include to the extent possible the information in the Recommended Report Information Form attached to this Procedure.

3. If Esaote Personnel believe in Good Faith that a Reported Matter has not been dealt with in accordance with this Procedure, Esaote Personnel should contact the 231 Supervisory Body.

#### 7 RESOLUTION PROCESS

- 1. The person who receives the Reported Matter will notify the person making the report and acknowledge the Reported Matter within [5] business days of receiving it, unless it is an anonymous report.
- 2. Details of the Reported Matter will be sent as soon as possible to Compliance Officer, unless it was Compliance Officer who initially received the Reported Matter. Compliance Officer will immediately record the Reported Matter in a Report register and open a file to be kept in a safe location to protect the confidentiality of the Reported Matter and person making the report. If Compliance Officer is somehow involved in the Reported Matter, the Internal Audit will replace the Compliance Officer in this process and involve the 231 Supervisory Body where necessary.

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### **MSG** Anti-Corruption

Ordinary reporting and confidential reporting

- 3. Compliance and the responsible line manager will discuss the Reported Matter to:
  - Identify the nature of the Alleged Misconduct and confirm it is covered by this Procedure.
  - Identify the most effective and appropriate process to handle the Alleged Misconduct.
    This may include an initial interview with the person making the report (if applicable),
    making initial inquiries to decide whether an investigation is required and if so,
    assigning an Investigator.
  - Estimate timelines for required action.
  - Decide whether the person making the report needs any additional support, in case of potential retaliation.
- 4. An Alleged Misconduct may be resolved without an investigation if agreed by Compliance Officer and the relevant head of business unit/function, or if it is covered by another Esaote procedure and more appropriately resolved under that procedure.
- 5. When a Reported Matter is resolved, the person making the report will be informed by the person who receives the report that is has been resolved and it will be reinforced that no retaliation against the person making the report will be tolerated. Appropriate disciplinary action will be taken as recommended by Compliance Officer pursuant to Model 231 provisions.
- 6. Compliance Officer will prepare a quarterly report for the Audit & Compliance Committee and for the 231 Supevisory Body on all Reported Matters including the status and resolution of Reported Matters for that quarter.

#### 8 INVESTIGATION PROCESS (IF APPLICABLE)

- 1. If it is determined under the Resolution Process that an investigation is required, an Investigator will be assigned to investigate the Reported Matter.
- 2. The Investigator will:
  - Determine the most effective and appropriate manner in which to handle the investigation.
  - Handle all matters in a professional, impartial and timely manner with the aim of either substantiating or invalidating the Alleged Misconduct.
  - Have access to all employees and documents needed to conduct the investigation.
  - Be authorized to ask for assistance from other departments or external parties to conduct the investigation.
  - Provide ongoing updates to the parties who appointed the Investigator on the progress of the investigation.
- 3. Anyone participating in the investigation (including suspects related to the Alleged Misconduct) must cooperate fully with the Investigator, including providing evidence to the

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Ordinary reporting and confidential reporting

Investigator. Participants must not disclose anything about the investigation to any party not authorized to have such information.

- 4. An investigation will be conducted in the strictest confidence by only involving people on a "need to know" basis and the Investigator will use all reasonable means to protect the confidentiality of the person making the report as well as any other parties involved. Information about an investigation will only be released to those authorized to have access to such information. Any person/s suspected of Alleged Misconduct will not be notified of their involvement in an investigation until it becomes necessary to do so.
- 5. After an investigation has been completed, a report will be prepared by the Investigator which will include all facts relating to the Reported Matter and Alleged Misconduct, analysis of the facts and recommended actions in relation to the Reported Matter and Alleged Misconduct. The report will be provided to the parties who appointed the Investigator.
- 6. The parties who appointed the Investigator will decide in conjunction with Compliance Officer and the Audit and Compliance Committee which, if any, external parties need to be notified about the outcome of the investigation (e.g. external auditors, law enforcement regulators, media).
- 7. All documents relating to an investigation will be kept in accordance with Esaote's document retention practices with the file opened for the Reported Matter in a safe location to protect the confidentiality of the Reported Matter and person making the report.

#### 9 APPROVAL PROCESS FOR EXCEPTIONAL CIRCUMSTANCES

Exceptions to this Procedure must be pre-approved in writing by the Audit and Compliance Committee and will only be granted in exceptional circumstances.

#### 10 RESPONSIBILITY

The Audit and Compliance Committee have overall responsibility for Reported Matters under this Procedure. Each head of business unit/function is responsible for ensuring compliance with this Procedure. Every employee is required to be familiar with and comply with this Procedure.



Reported Matter?

11. Other comments

# MSG Anti-Corruption Ordinary reporting and confidential reporting

#### 1 APPENDIX A – RECOMMENDED REPORT INFORMATION FORM

PER	RSONAL INFORMATION		
Nam	ne	Company	
Title	:	Email	
Depa	artment	Phone Number	
SUS	PECT/S INFORMATION		
Nam			
Title	,		
Depa	artment		
	npany		
	il and Phone Number		
	TNESS/ES INFORMATION		
Nam			
Title			
	artment		
	Company		
	il and Phone Number		
	TAILS OF ALLEGED MISCONDUCT	1101	
	cribe the Alleged Misconduct in the following w		
	ation, please complete a separate page for each.		
	Describe the Alleged Misconduct	136 1 1 1 1 /	
	Name the person/s who committed the Allegeo		
	State the department/s, business units or compa		
	8		
	When did the Alleged Misconduct occur and wh	nen did you notice it (including dates	
	and times)?		
	Are there any other parties involved? If yes, wh	•	
	Are there any specific amounts or other facts in		
	Do you have any evidence you can provide us?	· ·	
9. ]	Do you have any additional information that we	ould assist Esaote in resolving the	

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10. Are you concerned for your safety or that of any of the witness? If yes, why?



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#### 1 PURPOSE

Esaote recognizes that giving and receiving Gifts and Entertainment are often a common business or cultural practice intended to strengthen and build long term relationships. Esaote also recognizes that Travel (including transportation and accommodation) may be provided for certain attendees of Esaote facility tours, training events, clinical trials and other product consultation or demonstrations. However, Gifts, Travel and Entertainment (Benefits) are often inappropriately used to:

- Obtain or retain business or secure an improper advantage
- Exert undue influence or implied conditions on business relationships
- Violate Anti-Corruption Laws

In order for Esaote to maintain its ethical standards and meet our obligations relating to Anti-Corruption Laws, Esaote must ensure that Gifts, Travel, Entertainment and other Benefits are not given or received to inappropriately influence our interactions with Third Parties or obtain improper advantages.

The purpose of this policy is to set out the principles for giving or receiving Benefits to or from anyone Esaote does business with.

#### 2 SCOPE

This Procedure applies to all Esaote business activities, regardless the functions and wherever they are carried out. This includes full-time, part-time, contract and temporary Esaote Employees.

#### 3 GENERAL GUIDING PRINCIPLES - BENEFITS

#### The Basic Prohibitions

Never promise, offer, give, request or accept a Benefit that might exert undue influence or implied conditions (or the even the appearance) on the bona fide relationship between you and a Third Party or Health Care Professional.

Never make a payment or provide a Benefit directly or indirectly to a Commercial Entity, Government Official or Health Care Professional to obtain or retain business or secure an improper advantage.

Never give or receive bribes, kickbacks or other benefits to or from any Third Party or Health Care Professional to obtain or retain business or secure an improper advantage.

#### The Benefits Rule

Any and all permitted Benefits under this Policy (including Gifts, Travel and Entertainment) must be:

#### 1. Reasonable in value;

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- 2. Infrequent in nature;
- 3. Transparent and open;
- 4. Not given to influence or obtain an unfair advantage;
- 5. Respectful and customary.

All Benefits (including Gifts, Travel and Entertainment) given or received must be in accordance with this policy, the Benefits Rule as stated above and where applicable, the Gifts, Travel & Entertainment (GTE) Guidelines (refer to Appendix A).

However, all Esaote Employees must always apply personal judgment in good faith to decide whether a particular activity or expense is appropriate. For any questions, it should always be contacted the relavant Manager.

#### 3.1 Always, Everywhere

This Procedure applies at all times to Esaote Employees in any of the countries in which Esaote operates. It cannot be overridden by management or individual decisions, or express or implied expectations. It applies, without modification, during traditional gift-giving or holiday seasons and in connection with the planning of all company events.

#### 3.2 Appearance & Intention Matter

Always consider the appearance of Benefits being given or received, e.g. how Gifts, Travel or Entertainment may appear to other employees or persons outside Esaote as well as the reason the Benefits are being made or offered, e.g. are Gifts, Travel or Entertainment being offered to inappropriately influence a business decision or gain an improper advantage.

#### 3.3 Don't forget about Commercial Entities

This Procedure applies to both Government Officials and Commercial Entities. In other words, it applies to all parties acting with Esaote, both individual and collective, public and private (e.g. suppliers, consultants, service providers, etc.) or customers.

Whilst there is a lot of focus on laws in relation to the Benefits (including Gifts, Travel and Entertainment) given to and received from Government Officials, Esaote must also respect laws concerning commercial (private) bribery and corruption. It also makes good business sense to treat all of our business partners lawfully and in an ethical manner.

#### 3.4 No Cash

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It is forbidden to give or receive Benefits (including Gifts) that are money or cash equivalents (e.g. gift cards, certificates or coupons) at any time (e.g. during Chinese New Year, at weddings or funerals).

#### 3.5 Working out its Value

Sometimes it may be difficult to determine the value of Benefits (including Gifts, Travel and Entertainment).

- The value of a Gift is the greater of the actual cost to Esaote (i.e. what it costs Esaote to buy the Gift) or the face value of the Gift (i.e. what the Gift actually costs for any recipient).
- The value of Entertainment is the total actual cost of the Entertainment divided by the number of participants.

Where the value of other Benefits is unclear, relevant manager or Compliance Officer must be contacted.

#### 3.6 Strictest rule will apply

Where there is a discrepancy between the specific guiding principles contained in this Procedure, the rules contained in self-regulatory Codes of our the trade association(s) applicable to the geography concerned, and the governing rules applicable at your location of employment, the strictest rule will apply.

- Where the discrepancy is in relation to the permissible value of benefits given or received, the lowest value applies.
- Where the discrepancy is in relation to the conditions surrounding the giving or receiving of benefits, the more stringent conditions apply.
- Where the discrepancy is in relation to the type of third party with whom Esaote Employees are able to give or receive benefits from, the more stringent rule applies.

#### 3.7 Recipients have policies too

Many companies and government authorities also have policies on the giving and receiving of Gifts, Entertainment and other Benefits. Esaote Employees should always be sensitive to find out about and comply with these policies when giving or receiving a Benefit (including Gifts, Travel and Entertainment).



#### 4 DEFINITIONS

**Benefit** is anything that is offered, promised or given to a recipient and includes cash, cash equivalents, per diem expense payments, Gifts, Entertainment, travel, accommodation, business promotional activities, offers of employment, contributions to charities or political parties, investment opportunities, subcontracts, positions in joint ventures, favourable contracts, business opportunities and other similar items that are of value to the recipient.

A **Benefit Pre-Approval Request** is the form that should be used to request pre-approval of a Benefit, a copy of which is attached to this policy as Appendix B.

The **Benefits Rule** is the rule that requires that all Benefits are:

- Reasonable in value;
- Infrequent in nature;
- Transparent and open;
- Not given to influence or obtain an unfair advantage; and
- Respectful and customary.

A Commercial Entity is any commercial entity, firm, company or person that Esaote does business with.

**Entertainment** includes but is not limited to business meals, hospitality and/or entertainment.

**Event** means those programs and events that require travel and qualify for consideration of Esaote payment or reimbursement under this policy

The **GTE Guidelines** are the Gift & Entertainment Guidelines attached to this policy as Appendix A, which may be amended from time to time.

**Gifts** include anything presented as a token, social courtesy or to commemorate an occasion such as a holiday, birthday or special event as well as Esaote branded Gifts and other items of monetary value.

#### Government Official includes:

- Any official or employee of a government or government owned enterprise;
- Any official or employee of a government agency or regulatory authority;
- Any political candidate or member of a political party;
- Any government official acting in that capacity for a commercial enterprise;
- Any official or employee of a public international organization (e.g. United Nations, World Bank);
- Members of the Government Official's immediate family.

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**Health Care Professionals** are physicians, hospital purchasing personnel, other clinicians or any other person or entity in a position to purchase, influence the purchase of, or make referrals for Esaote products

**Per diems** means a payment (normally calculated on a daily basis) that genuinely estimates the reasonable cost of travel, meals, accommodation and other reasonable costs that a Third Party or Health Care Professional will incur to attend an Event.

A Third Party is any person, firm or company that does business for, with or on behalf of Esaote.

Travel includes transportation, accommodation and other expenses directly connected to the attendance of an Event.

#### 5 SPECIFIC GUIDING PRINCIPLES – GIFTS & ENTERTAINMENT

All Gifts, Travel and Entertainment given or received must be in accordance with this Procedure, the Benefits Rule and the GTE Guidelines (refer to Appendix A).

These guiding principles set out how Esaote Employees should do this whenever conducting Esaote business with Commercial Entities and Government Officials. However, Esaote Personnel must always apply personal judgment in good faith to decide whether a particular activity or expense is appropriate.

#### 5.1 Giving Gifts

Any Gifts that is promised, offered or given should be in accordance with section 1 of the GTE Guidelines (refer to Appendix A) AND consistent with the Benefits Rule.

GTE Guidelines (refer to Appendix A) AND c	consistent with the Benefits Rule.
Acceptable	Not Acceptable
Unless otherwise pre-approved, any Gifts	Esaote Employees should never promise,
promised, offered or given should be:	offer or give Gifts:
• Tangible and nominal, with a value of €	• To obtain or maintain a business
150 or less	relationship or opportunity for an
• Occasional, up to 4 times per year to the	improper advantage
same recipient	• In return for a benefit or decision
• Given for a legitimate purpose related to	• To provide any bribe, kickback or
work, business or customary practice	other benefit to the recipient
• Consistent with local and customary	<ul> <li>As money or cash equivalents</li> </ul>
practice	• In contravention of the known policy
• Ideally branded with the Esaote	of the recipient
Trademark (e.g. cups, umbrellas, pens	• To partners, spouses, relatives or
etc)	friends of a Esaote business associate
	without pre-approval

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#### 5.2 Receiving Gifts

Esaote discourages its employees from accepting ANY gifts. However, exceptional circumstances in local cultures may make refusal of gifts inappropriate. For these exceptional geographies: any Gifts accepted or received should be in accordance with section 2 of the GTE Guidelines (refer to Appendix A) AND consistent with the Benefits Rule.

#### Acceptable

Unless otherwise pre-approved, any Gifts accepted or received should be:

- Tangible and nominal, with a value of € 150 or less
- Occasional, up to 2 times per year from the same company or entity
- Given for a legitimate purpose related to work, business or customary practice
- Consistent with local and customary practice

#### Not Acceptable

Esaote Personnel should never accept or receive any Gifts given:

- To influence or designed to influence you to create or maintain a business relationship or opportunity for an improper advantage
- To influence or designed to influence you to provide a benefit or make a decision for an improper advantage
- In return for a benefit, decision, advantage or favour
- To provide any bribe, kickback or other benefit to you or any other party
- As money or cash equivalents

Esaote Personnel must always immediately report to the relevant Manager any Gift that are offered, accepted or received.

Esaote reserves the right to claim any Gift given to its employees as company property.

#### 5.3 Entertainment

Any Entertainment provided or accepted should be in accordance with section 3 of the GTE Guidelines (refer to Appendix A) AND consistent with the Benefits Rule.

#### Acceptable

Unless otherwise pre-approved, Entertainment provided or accepted should be:

- Reasonable meals and/or Entertainment, with a value of € 150 per person (including tip) or less
- Occasional, up to 4 times per year with the same company or entity
- Be directly related or associated with business and serve a legitimate business purpose, such as developing a potential or actual business relationship
- Consistent with local business practice

#### Not Acceptable

You should never provide or accept any Entertainment that is:

- Lavish or extravagant in nature
- Provided at places of ill repute, such as strip clubs and bars or other places providing services of a similar nature
- Designed to influence or will influence a business relationship or opportunity for an improper advantage
- Designed to influence or will influence a decision or obtain a benefit for an improper advantage
- In return for a benefit, decision, advantage or favour
- To provide any bribe, kickback or

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other benefit

• In contravention of the known policy of the recipient

Esaote Employees must always immediately report to the relevant Manager any Entertainment that are offered or accepted that does not meet the requirements in this section – either because it is inconsistent with what can be accepted or received or it is consistent with what it should not be accepted or received.

Entertainment expenses are not considered Gifts if Esaote employees are present (e.g. if a Esaote Employee takes somebody to dinner, that would be considered Entertainment whereas if the Esaote employee gave a gift certificate or voucher or paid for dinner but was not there, that would be considered a Gift).

#### 5.4 Travel

Any Travel provided or accepted should be in accordance with section 4 of the GTE Guidelines (refer to Appendix A) AND consistent with the Benefits Rule.

#### Acceptable

- Reasonable and at a level no greater than permitted for equivalent Esaote employees
- Involve executing or performing a contract or be in the normal course of promoting, demonstrating or explaining Esaote business
- It is of value to advancing Esaote's scientific knowledge, physician competency or training on the use of Esaote products and devices

#### Not Acceptable

Esaote must never pay or reimburse travel that:

- Is for a relative, associate or other guest of the recipient
- Includes side trips or stopovers

#### 5.5 Per Diems

Esaote strictly prohibits the payments of per diems to any Third Party, Government Official, Health Care Professional or Esaote Employee. Requests for per diems must be rejected.

#### 6 APPROVAL AND REIMBURSEMENT PROCESS

All Benefits (including Gifts, Travel and Entertainment) must be approved in accordance with this Procedure and the GTE Guidelines (refer to Appendix A).

The following details must be provided in a Benefit Pre-Approval Request as they apply to the particular Benefit. For more details, see the GTE Guidelines (refer to Appendix A) and Appendix B:

- Whether the Benefit relates to a Gift/meal/Entertainment/other
- Nature and purpose of the Benefit

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- Date the Benefit was given or received
- Whether the recipient/giver was a commercial entity or individual or Government Official
- Amount and/or value of the Benefit/s
- Amount received per recipient
- Details on each recipient including full name, title, department and Company/Government Authority

A Benefit Pre-Approval Request as well as the required pre-approval must be in writing (e.g. through email).

For Entertainment expenses where more than one Esaote person employee is present, the most senior employee must pay for and submit the expense claim for reimbursement.

All expense claims relating to Benefits must include any written pre-approval required under this policy and the GTE Guidelines (refer to Appendix A) as well as supporting documentation (including all receipts, invoices, bills etc). If written pre-approval is not required, the expense claim must also include the following details in writing:

- Whether the Benefit relates to a Gift/meal/Entertainment/other
- Nature and purpose of the Benefit
- Date the Benefit was given or received
- Whether the recipient/giver was a commercial entity or individual or Government Official
- Amount and/or value of the Benefit/s
- Amount received per recipient
- Details on each recipient including full name, title, department and Company/Government Authority

In exceptional situations where written pre-approval should have been obtained in relation to a Benefit but was not obtained, Esaote Personnel must obtain approval immediately from the relevant person.

#### 7 APPROVAL PROCESS FOR EXCEPTIONAL CIRCUMSTANCES

Exceptions to this Procedure must be pre-approved in writing by the Esaote Compliance Officer, and will only be granted in exceptional circumstances.

#### 8 EXPENSE MONITORING

Compliance Officer will monitor all expense claims relating to Benefits (including Gifts, Travel and Entertainment) whose request is sent to Compliance Officer for approval, in order to ensure appropriate approvals have been obtained and that all expenses are properly documented.

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Any expense claims that do not comply with Esaote Model 231, Code of Conduct and Anti-Corruption Regulations (including this Procedure), will not be paid and will be returned to the employee making the expense claim for additional approvals or documentation.

#### 9 REPORTING VIOLATIONS

Any suspected violations of this policy must be immediately reported to the relevant manager or through the various communication channels referred to in the Procedure on Ordinary Reporting and Confidential Reporting. No retaliation will be tolerated for reporting, in good faith, any suspected violation of this policy.

Managers receiving reports of suspected violations of this policy must immediately provide all of the details reported to them to the Compliance Officers.

Esaote Employees who violate the spirit or letter of this Procedure may be subject to disciplinary action. It is not an acceptable defence to a violation of this policy that the Esaote Employee was unaware that the subject circumstances were unlawful or a violation of this Procedure.

#### 10 RESPONSIBILITY

The head of each business unit/branch/office is responsible for ensuring compliance with this Procedure. Every Employee and Manager is required to be familiar with and comply with this Procedure. Any questions about this policy should be discussed with the relevant Manager.



#### APPENDIX A – GTE GUIDELINES

1.	GIVING GIF	TS				
Type of Gift		Conditions  All conditions must be satisfied for a Gift to be promised, offered or given. If a condition is not satisfied, the relevant preapproval must be obtained BEFORE the Gift is given.		Pre-Approval Required?	Allowed?	Pre- Approval and/or Expense Claim Documentation
1.	Esaote Branded Products (e.g. promotional items)	Gift must be:  ♦ Branded with Esaote Trademark  ♦ Nominal value (<€150)  ♦ Occasional (Maximum of 4 per year per recipient)  ♦ Given for a legitimate purpose – related to work, business or customary practice  ♦ Consistent with local/customary practice	Gift must NOT be:  ♦ Money or cash equivalents  ♦ To obtain/maintain a business relationship/ opportunity for an improper advantage  ♦ In return for a benefit/decision  ♦ To provide a bribe/ kickback/other benefit  ♦ In contravention of the recipient's gift policy	No	Yes	<ul> <li>♦ Supporting documentation (e.g. request to Esaote Marketing)</li> <li>♦ Expense claim with details on the Gift/expense:         <ul> <li>Relates to a Gift/meal/Entertainmen t/other</li> <li>Nature and purpose</li> <li>Date given</li> <li>Recipient was a Commercial Entity or Government Official</li> <li>Amount and/or value</li> <li>Amount per recipient</li> <li>Name, title, department and entity for each recipient</li> </ul> </li> </ul>
2.	Non Esaote Branded Products/ General Gifts	Gift must be:  Tangible  Occasional (Maximum of 4 per year per recipient)  Given for a legitimate purpose related to work, business or customary practice  Consistent with local/customary practice	Gift must NOT be:	<€150 No	Yes	<ul> <li>→ Written preapproval (if applicable) or the expense claim with details on the Gift/expense:</li> <li>• Relates to a Gift/meal/Entertainment/other</li> <li>• Nature and purpose</li> <li>• Date given</li> <li>• Recipient was a Commercial Entity or Government Official</li> <li>• Amount and/or value</li> <li>• Amount per recipient</li> <li>• Name, title, department and entity for each recipient</li> </ul>

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ENTERTAINMENT

### **MSG Anti-Corruption**

Gifts, Travel, Entertainment & Other Benefits

Gift giver

		<b>*</b>	Supporting documentation
			(e.g. receipts, invoices)

#### RECEIVING GIFTS Allowed to Allowed Pre- Approval Accept? to Keep? Documentation All conditions must be satisfied for a Gift to be accepted or received. If a condition below is not satisfied, the Gift must not be accepted and you must immediately report the matter to your manager. If approval is required to accept the Gift, this should be obtained BEFORE the Gift is accepted. Gift must be: Gift must NOT be: <€150 Yes Tangible Money or cash equivalents Yes Occasional Designed to create/maintain a Not Applicable business relationship/ (Maximum of 2 per year per company/entity) opportunity for an improper Received for a legitimate advantage Designed to provide a benefit purpose - related to work, Written pre-Between €150 Yes, with or make a decision for an business or customary -200manager approval practice improper advantage Yes, with prepre-Details on the Consistent with In return for a approval approval by Gift: benefit/decision/ local/customary practice manager Nature and advantage/favour purpose To provide a bribe/ Date accepted kickback/other benefit In contravention of the or received recipient's gift policy Given by a Commercial Entity or Government Official Amount and/or value Name, title, department and entity of

5. ENTERTAINMENT					
Type of Entertainment  Conditions  All conditions must be satisfied for Entertainment to be provided or accepted. If a condition below is not satisfied, the Entertainment must not be provided or accepted and ye must immediately report the matter to your manager. If prapproval is required to provide or accept Entertainment, the should be obtained BEFORE the Entertainment is provided or accepted.		ndition helow is not satisfied, the provided or accepted and you matter to your manager. If pre- tle or accept Entertainment, this	Pre-Approval Required?	Allowed?	Pre- Approval and/or Expense Claim Documentation
All Entertainment (e.g. business meals, hospitality and/or entertainment)	Entertainment must be:      Occasional     (Maximum of 4     per year per     company/entity)      Directly related or     associated with     business      Serve a legitimate     business purpose      Consistent with     local business	Entertainment must NOT be:      Lavish/extravagan     t     Provided at places     or ill repute or of     a similar nature     Designed to     influence a     business     relationship/     opportunity for an     improper	<€150/ person No	Yes	<ul> <li>❖ Supporting documentation (e.g. receipts, bills)</li> <li>❖ Written preapproval (if applicable) or the expense claim with details on the Entertainment/expense:</li> <li>• Relates to a meal/ Entertainmen</li> </ul>

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practice  advantage  Designed to influence a decision or obtain a benefit for an improper advantage  In return for a benefit/decision/advantage/favour  To provide a bribe/kickback/other benefit  In contravention of the recipient's gift policy	provided or accepted  Involved a Commercial Entity or
--	---

4. TRAVEL				
Type of Entertainment	Conditions  All conditions must be satisfied for Travel to be provided or accepted. If a condition below is not satisfied, the Travel must not be provided or accepted and you must immediately report the matter to your manager. If pre-approval is required to provide or accept Travel, this should be obtained BEFORE the Travel is provided or accepted.	Pre-Approval Required?	Allowed?	Pre- Approval and/or Expense Claim Documentation
All Travel (e.g. transportation and/or accommodation)	Travel must:  ♦ Be reasonable and at a level no greater than permitted for equivalent Esaote employees  ♦ Involve executing or performing a contract or be in the normal course of promoting, demonstrating or explaining Esaote business  ♦ Be of value to advancing Esaote's scientific knowledge, physician competency or training on the use of Esaote products and devices  ♦ Include a written invitation which is accepted by the attendee and their employer in writing		Yes  Approval by Board of Directors also required	<ul> <li>♦ Supporting documentation (e.g. receipts, bills)</li> <li>♦ Agenda of the Event</li> <li>♦ Written invitation</li> <li>♦ Written acceptance by the attendee and their employer</li> </ul>

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#### APPENDIX B – BENEFIT PRE-APPROVAL REQUEST

To obtain pre-approval of a Benefit in accordance with the Gifts, Entertainment & Other Benefits Policy, please complete this form in full and provide it to the relevant person for approval. For further information, you should refer to section 5 of the Gifts, Entertainment & Other Benefits Policy and the GTE Guidelines in Appendix A of this Procedure.

Name		
Department		
Email and Phone Number		
Benefit Details		
What does the Benefit relate to?	Gift	Meal
	Entertainment	Other
		(please
		specify)
What is the nature and purpose of the Benefit?		
Will the Benefit be given or received?	Given	Received
Date the Benefit will be given or received?		
Is the recipient/giver a Commercial Entity or	Commercial Entity	Government
Government Official?		Official
What is the amount and/or value of the Benefit?		
What is the amount and/or value given/received per R	ecipient (if applicable):	)
Please provide full details on each recipient/giver inclu-	ıding:	
Name (in full)		
Title		
Department		
Company/Government Authority		
These details can be provided on a separate sheet and be att		
Employee Signature	Date	
Approved	Yes	
	No	
	Special Conditions/Con	nments:
Approver Name		
Approver Signature	Date	

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#### 1. SCOPE AND PURPOSE

#### 1.1. Scope

This Procedure is part of the Esaote Anti-Corruption Regulations provided for under the Management System Guideline Anti-Corruption.

The purpose of this Procedure is to regulate the principles and rules to be followed by Esaote and its Subsidiaries in the negotiations, conclusion and execution, with one or more Partners, of Joint Venture Agreements.

#### This Procedure sets forth:

- what type of due diligence is necessary before a decision is made whether to enter into a Joint Venture Agreement with a potential Partner;
- which clauses, representations and warranties must be included in contractual documentation regarding the Joint Venture; and
- how to implement adequate procedures and control systems once the Joint Venture is established in order to prevent the commission of crimes of corruption and other crimes.

In this context, the following are the objectives of the application of this Procedure:

- to ensure that Esaote and its Subsidiaries conclude Joint Venture Agreements with Partners with outstanding reputation for honesty and correct business practices, who share Esaote's ethical values and respect for the law, and who are ready to act only in accordance with Anti-Corruption Laws and international best practices;
- to ensure that the procedure of negotiation and management of the Joint Venture Agreements are carried out according to criteria of diligence, transparency, correctness and in compliance with Anti- Corruption Laws, all applicable laws, the Code of Conduct, the Model 231, this Procedure and the Management System Guideline Anti-Corruption;
- to ensure the continuous updating and improvement of Esaote internal control system;
- to pursue criteria of pertinence and economic advantage.

#### 1.2. Support

Details of applicable laws and Anti-Corruption Laws may change at any time, so it is important to obtain up-to- date legal advice before making any commitment on behalf of Esaote.

#### To this purpose:

questions with respect to the content of Anti-Corruption Laws, the Code of Conduct, or any
of the matters discussed in this Procedure, or their application to specific situations, and/or

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 questions with respect to the financial information and internal controls provisions of the Anti- Corruption Laws, or any of the matters discussed in this Procedure, or their application to specific situations

or should a recipient of this Procedure have doubts whether an agreement to be entered into with one or more Partners shall be ruled by this Procedure, it shall contact the Compliance Officer that shall take steps to evaluate whether the negotiation, conclusion and/or implementation of the agreement submitted to its attention is subject to this Procedure.

#### 2. APPLICATION

This Procedure has been reviewed and approved by the Board of Directors of Esaote and is mandatory for Esaote and all its Subsidiaries.

Moreover, Esaote will also use its influence, to the extent reasonable under the circumstances, to cause companies and entities in which Esaote has a non-controlling interest to meet the standards set up in this Procedure by adopting and maintaining an adequate system of internal controls consistent with the requirements established by the Anti-Corruption Laws. In any case, the representatives indicated by Esaote in such companies and entities shall use his best efforts to cause the standards set up in this Procedure to be adopted.

Relevant circumstances include the degree of Esaote ownership of the company or entity and the laws and regulations governing the business operations in the country in which the company or entity is located or the activities are based.

#### 3. REFERENCE

- Code of Conduct;
- Model
- "Management System Guideline Anti-Corruption"

#### 4. **DEFINITIONS**

**ANTI-CORRUPTION LAWS**: the Italian Criminal Code, the Legislative Decree 231 and other applicable provisions, the FCPA, the UK Bribery Act, other public and commercial anti-bribery laws in effect around the world, and international anti-corruption treaties such as the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions, and the United Nations Convention against Corruption.

**CODE OF CONDUCT**: Esaote's Code of Conduct.

DECREE 231 Italian Legislative Decree June 8, 2001, No. 231, as amended from time to time.

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**ESAOTE**: Esaote S.p.A. and its Subsidiaries.

**COMPLIANCE OFFICER**: A resource within the Company entrusted with the management and implementation of policies aimed at avoiding or reducing the exposure to liability for any violation of national or international regulations, decisions of competent authorities or other applicable rules of conduct. The Esaote Compliance Officer: (i) ensures knowledge of applicable regulations; (ii) makes proposals, preparation and update of compliance policies for preventing any corporate conduct that may be contrary to regulations; (iii) acts as reference person for Group companies; (iii) reports on the implementation and monitoring of compliance policies to the Board of Directors; (iv) assists the 231 Supervisory Body in relation to any Legislative Decree 231 issue; and (v) carries out communication and training on compliance policies.

**ESAOTE PERSONNEL**: the directors, officers, members of corporate bodies, managers and employees of Esaote.

**ESAOTE REPRESENTATIVE(S)** Person(s) who will represent Esaote or its Subsidiary within the scope of the Joint Venture.

**FAMILY MEMBER**: the Public Official's spouse; the Public Official's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; the spouse of any of these people; and any other individuals who share the same household; and the private party's spouse; the private party's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; the spouse of any of these people; and any other individuals who share the same household.

**INCORPORATED JOINT VENTURE(S) AGREEMENT** Any agreement aimed at establishing legal entities in which the Partners have shareholdings or quotas in proportion to their interests in the joint venture and which have an autonomous legal status.

**JOINT VENTURE(S) AGREEMENT** Any agreement aimed at establishing joint ventures, consortia, temporary associations of companies (Associazioni Temporanee di Imprese, ATI), associations, cooperation agreements or other entities with or without legal status in which Esaote any of its Subsidiaries holds an interest.

**JOINT VENTURE LEADER** Partner of an Unincorporated Joint Venture which is entrusted with the relationship with the final client or which has the power to act on behalf of, or represent, Esaote or its Subsidiary.

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**MANAGER:** The most senior manager of the department, of the area or of the operative company involved in the operations that will be carried out through the Joint Venture.

**MODEL 231**: the Model concerning the organization, management and controlling activities of Esaote (ex Legislative Decree 231 of 2001) approved by the Board of Directors of Esaote S.p.A..

**NOTE** Note drafted and signed by the Manager in accordance with Section 5.1.2.

**PARTNER OR PARTNERS** One or more third parties with whom Esaote and/or any of its Subsidiaries intends to establish a Joint Venture, as defined above.

**PROCEDURE** This Procedure, together with its Appendixes and Annexes.

**PRINCIPAL** Each owner (partner or shareholder) of the Partner, each member of the board of directors of the Partner, each officer or managing director of the Partner, each individual who is a beneficial owner of the Partner or each individual who is able to exercise control over the Partner through any arrangement, and each individual (employees and consultants) working for the Partner who is principally responsible for operations and/or activities under the Joint Venture Agreement..

#### **PUBLIC OFFICIAL:**

- (a) anyone who performs public functions in a legislative, judicial or administrative capacity;
- (b) anyone acting in an official capacity for or on behalf of (i) a national, regional or local government, (ii) an agency, department or instrumentality of the European Union or of an Italian or a non-Italian national, regional or local government, (iii) an Italian or a non-Italian government-owned or government-controlled or government-participated company, (iv) a public international organization such as the European Bank for Reconstruction and Development, the International Bank for Reconstruction and Development, the International Monetary Fund, the World Bank, the United Nations or the World Trade Organization, or (v) an Italian or a non-Italian political party, member of a political party, official or candidate for political office;
- (c) anyone in charge of providing a public service, i.e. whoever performs a public service for whatever reason, where public service means an activity that is governed in the same way as a public function, except that the power vested in the latter is absent. The performance of basic ordinary tasks and exclusively manual work is excluded.

**QUESTIONNAIRE** Questionnaire to be filled out by Partner pursuant to Section 5.1.1.

**RELEVANT CONTACT** Any direct or indirect contact related to:

a) influencing any legislative, executive branch, judicial or other public policy body or personnel

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- or any political party or public international organization;
- b) any governmental inquiry, inspection, audit, assessment, licensing, permitting, registration or similar administrative, regulatory or enforcement action;
- any potential or actual government contract or other transaction or business involving a
  governmental body or corporation owned or controlled by a government, a political party or
  a public international organization;
- d) entertainment, training, reimbursement of expenses or gifts for a Public Official
- e) any other negotiation, settlement or consultation with a government body or public international organization or Public Official, other than consultation that does not involve advocating any position if such consultation is with a Public Official acting in a ministerial, administrative or legal capacity and solely for the purpose of seeking an interpretation or advisory opinion regarding application of regulations, explanation of procedures for filing documents with the government, or legal aspects of a private transaction; and
- f) similar activities.

**SUBSIDIARY**: any entity that is directly or indirectly controlled by Esaote S.p.A.(1) in Italy and abroad.

**UNINCORPORATED JOINT VENTURE(S) AGREEMENT** Any Joint Venture Agreement which is not an Incorporated Joint Venture Agreement, such as an agreement in which the cooperation among the Parties is on a split-liability basis, i.e. where economical risks, pricing, invoicing, payments, taxes and duties, book-keeping and the like are separate and independent for each Partner.

#### 5. PROCEDURES AND RESPONSIBILITIES

In the case of one of the Business Unit or Area of Esaote, within its area of responsibility, finds it necessary to enter into a Joint Venture with one or more Partners, it must follow the due diligence and procedures set out below.

No Esaote Personnel may commit to or enter into a Joint Venture Agreement, without prior approval pursuant to the process established under this Section.

#### 5.1. Due Diligence on the Partner

Before Esaote or any of its Subsidiaries enters into a Joint Venture Agreement, a due diligence must be conducted on any potential Partner.

The responsibility for the due diligence on the Partner(s) is given to the Manager.

(1) The list of these companies is that included in the appendix "Controlled subsidiaries" of the most recent approved consolidated financial statement.

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If the Manager does not believe necessary to conduct a due diligence or an in-depth due diligence on any of the Partners, he will consult with the Compliance Officer and submit to the same a note specifying in writing the reasons for which he does believe a due diligence is not necessary or a reduced due diligence will be sufficient for the purposes of this Procedure.

The due diligence could not result necessary or a reduced due diligence could result sufficient, for example, due to the customs of the relationship with the Partner, its recognized standing, its demonstrated reliability, the Partner's excellent ethical reputation and/or in the case the Joint Venture will:

- a) not market or sell products, services to public entities or government customers,
- b) not engage in lobbying activities before Public Officials,
- c) not seek regulatory approvals from or be subject to regulatory oversight by Public Officials,
- d) not have other Relevant Contacts with Public Officials; or
- e) be an Unincorporated Joint Venture where none of the Partners will have the power to act as Joint Venture Leader.

In case of Unincorporated Joint Ventures where Esaote or its Subsidiary acts as Joint Venture Leader, the due diligence will consist of a global database search (e.g. relevant names identification and ownership, financial references, criminal record check, debarred or restricted parties lists, potential Partners experience with Esaote, internet search, as indicated in Attachment A "Due Diligence Guidelines").

The Compliance Officer shall specify in writing if it believes that (i) it is necessary to conduct an indepth due diligence, or (ii) no due diligence or a reduced due diligence will be sufficient, specifying in that case which of the due diligence requirements listed in Section 5.1.1. below can be waived or modified.

The Manager may appoint an external firm to conduct the Due Diligence or the reduced Due Diligence as aforesaid as required by this Procedure.

#### 5.1.1. Standard Due Diligence Requirements

The due diligence shall be conducted by the Manager, also through the appointed external firm based on the following criteria:

- a) the potential Partner shall be asked to fill out the Questionnaire, attached to this Procedure as Attachment C, and to provide the relevant documents indicated therein;
- b) further information on the Partner shall be collected from public sources and other sources available to the company. The extent of such information gathering shall depend on the particular circumstances, such as the company's knowledge of the Partner based on prior dealings, the importance of the project for which the Joint Venture shall be

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- established, the risk of the country where the Joint Venture will operate, the role that the Partner will have in the Joint Venture management and, in general, the perceived level of risk.
- c) the Partner's chain of control/ownership and the information collected shall be confirmed and verified as appropriate through public sources, internet or external sources (including Embassies, Consulates, international exchange agencies, chambers of commerce, etc.), according to the Due Diligence Guidelines set out in Attachment A "Due Diligence Guidelines":
- d) an important aspect in conducting the due diligence is to pay attention to the Red Flags indicated in Attachment B:"Red Flags".

#### 5.1.2. Drafting the Note

The data and information gathered through the due diligence exercise shall be adequately documented and collected in a Note signed by the Manager and submitted to Compliance Officer according to the following Section 5.1.3.

The Note shall also indicate.

- a) the reasons for which the creation of the Joint Venture is considered essential or, in any case, useful for the pursuit of the corporate purpose of Esaote and/or its Subsidiary and/or for the development of a project in relation to which the Joint Venture is to be established:
- b) how the Partner's name came about, which external subject, if any, recommended the Partner, and the Esaote corporate Business Unit/Area that received the recommendation and gave the Partner's name to the Manager;
- the declaration that due diligence was completed and that verifications were conducted in compliance with the principles contained in this Procedure, the Management System Guideline Anti-Corruption and any other applicable Esaote procedures and applicable law;
- d) a description of any Red Flags or particular risks emerged or identified during the due diligence;
- e) in case a reduced or no due diligence has been conducted, the specification of which controls have been carried out and details of the indication obtained by the Compliance Officer on if and how conduct a reduced due diligence or to omit any due diligence;
- f) the names of the persons chosen, according to Section 5.2 for conducting the negotiation in the name and behalf of Esaote or its Subsidiary;
- g) the declaration that the persons indicated under letter f) above personally interviewed the Partner's representative in view of the conclusion of the agreement and that, also in consideration of the results of the interview, there is no reasonable indication that the Partner will violate, if appointed as Joint Venture's Leader, or will cause the Joint Venture to violate the Anti-Corruption Laws;
- h) information on any current, past and pre-existing relationship between Esaote and the Partner;
- i) the specific description of the activities that will be carried out by the Joint Venture and of the structure of the Joint Venture;
- j) the list of the sources that have been used to verify the information contained in the Questionnaire and to conduct the due diligence.

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### 5.1.3. Note verification and decision

The Note, including all its supporting documentation, shall be sent to the Compliance Officer, which shall review the results of the due diligence also on the basis of the Due Diligence Guidelines contained in Attachment A "Due Diligence Guidelines" and the existence of possible Red Flags as indicated in Attachment B: "Red Flags" and if necessary suggest to the Manager any appropriate further actions (e.g. conducting further due diligence).

The Manager shall transmit the Note, the indication provided by the Compliance Officer pursuant to the previous Section and the outcome of any further action [and the draft of the Joint Venture Agreement, drafted in accordance with subsequent Sections 5.2] to the Board of Directors of Esaote or to the Board of Directors of the Subsidiary for approval.

## 5.2. NEGOTIATION PROCESS AND REQUIREMENTS

Once the choice of the Partner has been finalized according to Section 5.1, the Joint Venture Agreement shall be negotiated according to the following principles.

Negotiations of the Joint Venture Agreement shall always be carried out by at least two people, both chosen by the Manager, who shall both not be part of the same corporate function and shall not have a hierarchical relationship with each other.

No Esaote Personnel may commit to or enter into the Joint Venture agreement with a Partner, without prior approval pursuant to the process established under this Section, and in particular, under Section 5.2.2.

### 5.2.1. Joint Venture Agreement

If Esaote or its Subsidiary will exercises control over the Joint Venture, Esaote or its Subsidiary shall cause the Joint Venture to adopt the Code of Conduct, a Model 231 (if necessary), the Management System Guideline Anti-Corruption, the Esaote Anti-Corruption Regulations. In the adoption and implementation of an adequate internal control system, the risk factors related to the country of incorporation of the Joint Ventures and the country in which the Joint Venture will operate shall be taken into particular consideration.

If Esaote or its Subsidiary will not exercise control over the Joint Venture Esaote or its Subsidiary shall use its influence, to the extent reasonable under the circumstances, to cause the Joint Venture (a) to adopt principles of ethical conduct, including with respect to anti-corruption policies, in line with those on which Esaote's activity is based and (b) to meet the standards set up in the Esaote Management System Guideline Anti-Corruption by adopting and maintaining an adequate system of internal accounting standards and controls that are consistent with the requirements established by the Anti-Corruption Laws. Relevant circumstances

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include the degree of Esaote's ownership of the Joint Venture and the laws and regulations governing the business operations of the country in which the Joint Venture is located or the activities are based.

Esaote Personnel, in negotiating the Joint Venture Agreement, shall use their best efforts to include in such agreement the following provisions:

- a) the commitment by the Joint Venture's Leader to adopt, and/or the commitment by each other Partner to cause the Joint Venture to adopt and to keep in place an effective and appropriate internal control system and a compliance program for the prevention of corruption, money laundering and other crimes in accordance with the Anti-Corruption Laws;
- b) the commitment by each Partner to supervise and constantly monitor the implementation and effective operation of the Joint Venture's internal control system and compliance program and to inform Esaote or the Subsidiary promptly of any potential deficiency or Red Flag;
- c) the commitment by the Joint Venture's Leader to act, and the commitment by each other Partner to use best efforts to cause the Joint Venture to act, in compliance with the Anti-Corruption Laws, the Joint Venture's internal control system and the Joint Venture's compliance program and that they shall never pay, directly or indirectly, bribes to Public Officials or their Family Members or to shareholders, partners, or members of the corporate bodies of the counterparty with which the Joint Venture proposes to operate in violation of applicable laws;
- d) the commitment by each Partners to cause all of its Principals that will carry on activities directly or indirectly related to/on behalf of the Joint Venture to act in compliance with the Anti-Corruption Laws, the Joint Venture's internal control system and the Joint Venture's compliance program including that such Principals shall never pay, directly or indirectly, bribes to Public Officials or their Family Members or to shareholders, partners, or members of the corporate bodies of the counterparty with which the Joint Venture proposes to operate in violation of applicable laws;
- e) the declaration/commitment of the legal representatives of each Partner<sup>1</sup>:
  - that neither he/she nor his/her Family Members, nor its Principals are Public Officials who
    are directly or indirectly related with the activities to be carried out by the Joint Venture;
  - to inform Esaote or the non-listed Subsidiary promptly if, after the conclusion of the Joint Venture Agreement: (i) he/she, or any of his/her Family Members, or any of its Principals are appointed as Public Officials and, as Public Officials, they will be directly or indirectly related with the activities to be carried out by the Joint Venture; (ii) of any event that could influence the circumstances pertaining to his/her own position or that of his/her Family Members or that of its Principals as represented to Esaote or the Subsidiary. The above statements will to be confirmed yearly or upon Esaote's or the Subsidiary's request;
- f) the commitment of each Partner to ensure that no Public Officials who are directly or indirectly related with the activities to be carried out by the Joint Venture or their Family Members will be

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- appointed directors of the Joint Venture or be hired by the same as employees, consultants or external consultants, intermediaries, agents;
- g) the veto right of Esaote or of the Subsidiary over the Joint Venture's decisions concerning the conclusion of agreements with, or otherwise the use or engagement of, intermediaries or business partners that will act on behalf of the Joint Venture with respect to activities relating to lobbying or obtaining regulatory approvals, or dealing with a public entity or that will likely have Relevant Contact with a Public Official in connection with its work on behalf of the Joint Venture;
- h) the indication by each Partner of the name of the person(s) who shall act as the representative(s) of the Partner in the Joint Venture or the undertaking to appoint such representative(s) at a later stage;
- the commitment of each Partner to select its representatives to the Joint Venture among individuals
  with outstanding reputation for honesty and correct business practices, as well as competence in the
  field of internal control systems;
- j) the commitment of each Partner to cause each of its representatives appointed in the Joint Venture to sign and adhere to the ethical commitments contained in the Joint Venture Agreement;
- k) Esaote's or the Subsidiary's right to have an audit carried out on the Joint Venture or on the Joint Venture Leader (and specifically on its activities related to the Joint Venture), in the event that Esaote or the Subsidiary has a reasonable belief that the Joint Venture or the Joint Venture Leader (in its activities related to the Joint Venture) may have violated Anti-Corruption Laws or its anti-corruption obligations;
- l) appropriate provisions to protect Esaote against the risk of violation of the anti-bribery clauses in case of change of control of each Partner;
- m) the non-transferability of the Joint Venture Agreement or of some of the obligations and rights contained therein by the Partner to third parties without Esaote's or the Subsidiary's prior written approval;
- n) without prejudice to the provisions of the "Administrative Liability" clause to be included in the Joint Venture Agreement, the right of Esaote or of the Subsidiary to terminate the Joint Venture Agreement and to obtain compensation for damages in case of breach by any of the Partners of the anti-corruption obligations, representations and warranties of the Joint Venture Agreement or in case of violations of the Anti-Corruption Laws.

Depending on the circumstances of each transaction, the Manager and the Compliance Officer shall jointly assess, from time to time, the need or opportunity of obtaining independent statements or opinions confirming; (i) whether the content, conclusion or performance of the Joint Venture Agreement violates any Anti-Corruption Laws; (ii) whether it is necessary to obtain a resolution or approval from any authority or any other subject for the conclusion or the performance of the Joint Venture Agreement.

Depending on the circumstances of each transaction, the Manager shall also request technical support to Compliance Officer before to waive or modify any of the clauses provided for in the Joint Venture Agreement

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under letter a) to n) above (specifying in writing the reasons for the request) and the clauses to be modified or waived.

### 5.2.2. Check

The final draft of the Joint Venture Agreement is sent by the Manager to the Esaote Compliance Officer, which shall check that the final draft complies with this Procedure.

## 5.3. IMPLEMENTATION OF THE JOINT VENTURE AGREEMENT

### 5.3.1. Choice of the Esaote Representative(s)

The implementation of the Joint Venture agreement is attributed to the Esaote Representative(s), who shall be selected among individuals with outstanding reputation for honesty and correct business practices, as well as competence in the field of internal control systems. The Esaote Representative(s) shall receive adequate training on Esaote's principles and rules of conduct, on Esaote's Code of Conduct, Model 231, the Management System Guideline Anti-Corruption, this Procedure and, in general, on the Anti-Corruption Laws.

## 5.3.2. Duties of the Esaote Representative(s)

The Esaote Representative(s) is/are responsible for:

- a) ascertaining and ensuring that the Joint Venture, the Joint Venture's Leader and the Partners always operate the Joint Venture according to criteria of maximum diligence, honesty, transparency, integrity and in compliance with the laws, and with the Joint Venture's internal control system and compliance program;
- b) monitoring also with the support of the Compliance Officer the effectiveness, efficacy and adequacy of the internal control system and compliance program adopted by the Joint Venture;
- c) monitoring the relationships with the Joint Venture's clients/counterparties, especially when they are public entities;
- d) monitoring, in particular, the relevance, pertinence, necessity, legality and correct execution of any agreement with intermediaries or business partners that will act on behalf of the Joint Venture with respect to activities relating to lobbying or obtaining regulatory approvals, or dealing with a public entity or that will likely have Relevant Contact with a Public Official in connection with their work on behalf of the Joint Venture, as well as the management by the Joint Venture of any activities involving charitable contributions, political contributions, gifts and entertainment to Public Officials;
- e) drafting a report, at least annually, to be submitted to the Compliance Officer concerning the activities carried out according to the preceding points;

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f) pointing out any possible Red Flag in the activities carried out by the Joint Venture, the Partner(s), the Partner's representatives, directors, managers, employees in connection with the Joint Venture and immediately alerting the Compliance Officer of any inadequacy, gap or suspected violation;

The activities indicated may also be carried out upon request and with the support of the Esaote Compliance Officer.

### 6. REPORTING VIOLATIONS

Any suspected or known violation of the Anti-Corruption Laws and of this Procedure must be reported immediately to one or more of the following:

- the employee's direct supervisor or, in case of violation on the part of the Intermediary, the Contract Manager;
- the Compliance and Audit Committee;
- the Compliance Officer;
- the 231 Supervisory Body;
- in any case, through the dedicated channels indicated in the Esaote Procedure on Ordinary Reporting and Confidential Reporting ("whistleblowing").

The direct supervisor, the Esaote Compliance Officer and the relevant Human Resources Department will consult to identify the course of action, including the application of disciplinary measures as appropriate.

### 7. CONTROLS AND RECORD KEEPING

The original documentation related to the selection and approval of the Joint Venture Partner(s) and the Joint Venture Agreements and the controls of compliance with this Procedure are to be saved for 10 years: as follows:

- for the Subsidiaries where a Esaote Compliance Officer is present: by the relevant Esaote Compliance Officer;
- for the other Subsidiaries: by the relevant Financial Officer.

### 8. DISCIPLINARY ACTIONS

Esaote shall use every reasonable effort in order to prevent any conduct in violation of Anti-Corruption Laws and/or this Procedure and interrupt and sanction any conduct to the contrary of Esaote Personnel.

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Esaote will take appropriate disciplinary action according to the Model and the collective employment agreements or other applicable national regulations, against any Esaote Personnel (i) whose actions are found to violate Anti-Corruption Laws or this Procedure, (ii) who unreasonably fail to detect or fail to report any violations according to the Management System Guideline Anti-Corruption or who retaliate against others who report such violations. Disciplinary action may include the immediate termination of employment.

#### 9. MONITORING AND ENHANCEMENTS

The Compliance Officer is responsible for oversight of this Procedure.

The Compliance Officer must periodically review this Procedure to ensure that it remains effective. In addition, the Functions, Contract Manager(s), Compliance and Audit Committee, Internal Audit and the company's independent auditors should recommend enhancements to the Procedure if gaps or weaknesses are identified, and as emerging "best practices" develop.

If a violation is found, the Compliance Officer will determine whether Procedure revisions or procedural enhancements would help prevent recurrence of the violation.

### 10. ATTACHMENT

These documents are part of this Corporate Standard Procedure:

- Attachment A: "Due Diligence Guidelines"
- Attachment B: "Red Flags"
- Attachment C: "Questionnaire"



#### ATTACHMENT A – DUE DILIGENCE GUIDELINES

In order to identify and document any reference to unethical or suspicious conduct of the potential Joint Venture's Partner, relationships with Public Officials and any information inconsistent with the one provided by the potential Joint Venture's Partner in the Questionnaire, the ownership and the information collected shall be reviewed and verified according to the following guidelines applicable to the circumstances. The following is intended to suggest some possible steps. Additional may be appropriate in certain circumstances.

- Relevant names identification: as a first step, start by reviewing the potential Joint Venture's Partner's Questionnaire, registrations and other documents to identify the full name of the potential Joint Venture's Partner, any related entities (e.g. parent companies, subsidiaries, branches and affiliates) and Principals (including owners, directors and officers representing the Partner for such potential Joint Venture's Partner).
- Official registry of Organizations: most official registries of companies and other organizations make their record available to the public in some form. Check ownership of companies etc., directorships, accounts and other relevant official documentation. Furthermore, if the owner is a trust company, check ownership of this company.
- Financial references. Request that the official registries provide the financial statements (including the balance sheet and profit and loss statements) of the last three years of the potential Joint Venture's Partner and of the related entities (in particular, the holding and the subsidiaries) and review them in order to verify, when possible, the information provided by the potential Joint Venture's Partner. If audited financial records for the previous three years are not available, a third party financial referee may be requested to state the length of the relationship and provide an opinion of reliability, financial capabilities and probity.
- Qualifications and membership of professional bodies: review the curricula vitae provided by the potential Joint Venture's Partner with the Questionnaire regarding the Principals and regarding managers, executives or key employees related to the contractual activity to be performed by the potential Joint Venture's Partner and verify, when possible, the information disclosed; in particular the experience and qualifications of such people should be verified through the potential Joint Venture's Partner's company search, relevant professional associations, Internet resources or contacting the former employer when deemed useful or necessary. Most educational or professional bodies will confirm qualifications especially if the prospective employer or contractor is able to produce a letter of authority from the individual or company concerned. It is important to view originals of certificates issued by official bodies and, where these bodies are not well know, to assess the authenticity of the issuing body.

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- Electoral records, local government business records, etc: local government offices and business libraries will make available public records of individuals (e.g. from electoral roll records) and businesses (e.g. from local business directories, etc). Verify the potential Joint Venture's Partner is recorded at the address given.
- O Criminal records: check criminal records for the potential Joint Venture's Partner and related entities (parent companies, subsidiaries, branches and affiliates), Principals and key management personnel or individual (if legally permissible in the country concerned).
- Debarred or restricted parties lists: information is available on some websites, and also via media searches, regarding companies and individuals barred from bidding on local national or international contracts. One such website with a debarred list for individuals and companies that have been judged to have committed acts of bribery or corruption in bid processes is the World Bank site: http://www.worldbank.org/html/opr/procure/debarr.html
- O Credit rating: there are a large number of international and local commercial organizations offering a credit rating services on individuals and organizations on a fee-paying basis. There are facilities available to check on bankruptcy or insolvency of individuals or companies. These will either be registers available to public scrutiny or listings made available on the Internet.
- Business history: identify through Internet or financial statements or other sources the business history and experience of the potential Joint Venture's Partner. In this respect, verify the business history and experience of the potential Joint Venture's Partners also through the business references provided by the same in the Questionnaire.
- Potential Joint Venture's Partners experience with Esaote: review the list of the agreement the potential Joint Venture's Partner currently has with Esaote or had in the past, if any. Subsequently, contact Esaote's key personnel that manages/managed each agreement, in order to request documentation on a previous potential Joint Venture's Partner's due diligence review if made and information regarding the potential Joint Venture's Partner's conduct in performing such agreements, and any Red Flags or issues arisen in connection to them.
- Media search: simple and cost-effective, the use of free and/or subscription databases to research the potential Joint Venture's Partner is recommended. If the potential Joint Venture's Partner has a website, this should be examined, as should useful government sites such as anti-cartel or anti-fraud, etc. In quotations, search each name on Google.com or comparable search engine. If the results are unreasonably large, click "search within results" and use appropriate terms to narrow the search, like: bribe, crime, charge, corrupt, fraud, slush fund, black money, money laundering. Search within the results using the narrowing terms individually. If the results remain unreasonably large, use the country to further narrow the search. Review the results list, identifying and printing any articles that

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implicate the potential Joint Venture's Partner, related entities or the Principals, in an inappropriate activity or indicate government services/employment or ties to the government or Public Officials, or that provide information that appears inconsistent with the information obtained through the potential Joint Venture's Partner's Questionnaire. Verify, if possible, such information also through other sources (including Embassies, Consulates, international exchange agencies, etc.)

O Anti-Corruption measures: search in the potential Joint Venture's Partner or related companies official web-site codes, procedures or policies addressing business ethics, anti-corruption compliance, entertainment or gifts for clients or Public Officials.



### ATTACHMENT B - RED FLAGS

The following are some of the Red Flags that are to be considered in conducting due diligence because they may indicate corruption. Although the presence of one or more Red Flags does not mean that improper conduct has already occurred or will occur, it does mandate greater scrutiny and implementation of safeguards.

- a) The circumstances in which the potential Joint Venture's Partner was identified or introduced are unusual or abnormal (e.g.: the potential Joint Venture's Partner was the only available Joint Venture's Partner, was introduced by someone who may be in conflict of interest, was strongly suggested by a government customer or a Public Official was involved or proposed for no apparent good reason, etc.);
- b) the potential Joint Venture's Partners carries out its business in a country or in an industrial sector with a reputation for bribery or corruption (be aware that the energy, construction and engineering industries are among those with a very high corruption risk). As to the country corruption risk please also refer to the Corruption Perceptions Index published by Transparency International (<a href="http://www.transparency.org/policy\_research/surveys\_indices/cpi">http://www.transparency.org/policy\_research/surveys\_indices/cpi</a>)(2);
- c) the potential Joint Venture's Partner or any of its Principals is domiciled and/or is a resident of a socalled tax haven or of a country with a high rate of corruption;
- d) the potential Joint Venture's Partner, if company, has an unusual corporate structure or was only recently incorporated;
- e) the potential Joint Venture's Partner is involved or proposed for no apparent good reason;
- f) the potential Joint Venture's Partner is duly registered but has no activity, no/poor staff, and its business address is only a "letter-box";
- g) the potential Joint Venture's Partner is owned by or employs a Public Official or a Public Official's Family Member;
- h) the potential Joint Venture's Partner or any of its Principals is in conflict of interest or has a questionable reputation or has been accused, prosecuted or convicted (especially in the case of bribery related offences, money-laundering or fraud) or has been debarred or blacklisted;

(2) Transparency International ("TI") is an international non-governmental organization dedicated to anticorruption efforts around the world. TI has more than 100 locally established national chapters and chaptersin-formation. These chapters work with governments, businesses and the media to promote transparency in elections, public administration, procurement and business. TI annually publishes a Corruption Perceptions Index ("CPI"). The CPI ranks more than 150 countries according to the degree to which corruption is perceived to exist among their public officials and politicians, ad determined by expert assessment and opinion survey.

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- the Partner has experience of unexplained or inadequately explained breakup of association with other companies;
- j) the Partner has a desire to keep the relationship secret or requires its identify not to be disclosed;
- k) the Partner insists on having sole control of any host country government approvals;
- l) a potential Joint Venture's Partner or third party representative suggests that he/she or it has or can make "special arrangements" with regards to the decision-making or action process at issue;
- m) the potential Joint Venture's Partner refuses to certify compliance with the Anti-Corruption Laws;
- n) the potential Joint Venture's Partner does not have an adequate internal control system nor adequate procedures for the prevention or identification of crimes of corruption and refuses to implement them;
- o) the potential Joint Venture's Partner refuses to provide information requested during a due diligence review process;
- p) the potential Joint Venture's Partner's business scope does not appear to be coherent/consistent with the scope of the Joint Venture;
- q) the potential Joint Venture's Partner does not have adequate resources to support the Joint Venture or its financial situation (capital invested and turnover) is questionable (for example: annual turnover/net assets are less than the services provided, significant losses, financial statements not subjected to an independent audit, discrepancies or inconsistencies in the financial statements);
- r) the potential Joint Venture's Partner has no/poor experience in relation to the contractual activity;
- s) according to the Joint Venture Agreement, the transaction involves a Public Official or a public entity with a reputation for corruption or who requests a payment or gift;
- the potential Joint Venture's Partner requests the returns under the Joint Venture Agreement to be paid: (i) in cash or; (ii) to an entity or individual rather than the potential Joint Venture's Partner; (iii) into a bank account registered in a country that is not the country where the potential Joint Venture's Partner resides or where the potential Joint Venture operate; (iv) into a ciphered bank account;
- u) the potential Joint Venture's Partner requests for an unusual transaction structure, inclusion of incorrect or unnecessary cost items or false documentation;
- v) the potential Joint Venture's Partner requests for unusually large payments, or payments that appear excessive and not reasonable;

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- w) the potential Joint Venture's Partner gives incomplete or inaccurate information in required disclosures for false invoices or other documentation;
- x) the laws of the country prohibit the use of an potential Joint Venture's Partner or restrict the form or amount of compensation.

The above list of Red Flags is not exhaustive. Other circumstances can arise that create a concern that corrupt activity may occur. Esaote Personnel who learn of circumstances that suggest the possibility of corruption should report the discovery of any such Red Flags immediately to the Esaote Compliance Officer.



## ATTACHMENT C – QUESTIONNAIRE

For the purpose of this questionnaire please make reference to the definitions provided for in section 4 of the Esaote Procedure on Joint Ventures.

The term "Principal" of the Joint Venture's Partner means each owner (partner or shareholder) of the Joint Venture's Partner, each member of the board of directors of the Joint Venture's Partner, each individual who is a beneficial owner of the Joint Venture's Partner, each individual who is able to exercise control over the Joint Venture's Partner through any arrangement, and each individual (employees and consultants) working for the Joint Venture's Partner who is principally responsible for operations and/or activities under the Joint Venture Agreement.

PLEASE SEE THE CHECKLIST AT THE END OF THIS APPLICATION FOR ADDITIONAL ITEMS THAT MUST BE SUBMITTED WITH YOUR APPLICATION. (PLEASE PROVIDE AN ENGLISH/ITALIAN TRANSLATION OF ANY DOCUMENT THAT IS IN ANOTHER LANGUAGE)

<b>A</b> .	CORP	ORATE INFORM	MATION				
	Joint Ve	enture's Partner nar	me:				
2.	VAT nu:	mber/Fiscal code:					
3.	under th	which the services ne Joint Venture ent will be performe	ed:				
ŀ.	Address Partner:	of the Joint Ventur	re's				
Tele	ephone:			Fax:			
E-m	nail:			Websi	ite:		
5.	Ventu	& Place of Joint re's Partner pration/registration					
	b) What	is the legal structure	of the Joint Ventu	re's Partner?	(check one)		
	Corp	oration:	Partnership:		Individu	al:	
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Other:	Please describe:	

6. Number of persons employed by your organization:

7. List all members of the board of directors or other managers or executives of the Joint Venture's Partner, their titles and their citizenship:

Name	Title	Citizenship

8 Management information for the Joint Venture's Partner: please describe the active management of the Joint Venture's Partner by position and what percentage of time is spent or will be spent on relevant operations and/or activities under the Joint Venture Agreement:

Name	Title	Citizenship

## B. OWNER INFORMATION

Please note that we need ownership information concerning the Joint Venture's Partner that identifies all of the individual owners of the Joint Venture's Partner, whether an individual owns the shares directly or indirectly through another legal entity. If a business entity (corporation, partnership, etc.) owns any portion of the Joint Venture's Partner, please trace ownership of all such entities back through as many layers as is necessary to identify all ultimate individual owners of such entities. Please do so on separate sheets of paper attached to this questionnaire. For any company in the chain of ownership that is traded on a public stock exchange, owners of five percent (5%) or more of the equity in the relevant company or who are otherwise known to the relevant company must be identified here. If any shareholders of less than five percent (5%) are not identified here for that reason, please also attach a written statement confirming that all unidentified shareholders acquired their shares through public trading.

Ownership (individual and/or business entity percentages) must equal 100%.

1. List owners of the Joint Venture's Partner

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Name	Citizenship	% Ownership

As part of our due diligence process, we need independent confirmation of the ownership information contained in your application. Please obtain a letter either from

ownership infor	mation set forth is		s, or (ii) a law fir tion, or (iii) a f	
government age Chamber of Con	ency or entity verif	ying the currer	nt ownership of	the compar
Are any other i through any arra	ndividuals able to	exercise control	over the Joint	Venture's 1
Yes:			No:	
If the answer is y	res, please explain:			
List affiliated cor	npanies:			
(a) Parent co	mpany/ies (if any):			
Full corporate Name	Jurisdiction of incorporation	Address	Telephone	Fax, webs any) and e address primary po
		Address	Telephone	any) and e

Subsidiary company/ies (i.e., companies owned, in whole or in part, by the Joint Venture's Partner, if any):

Fullcorporate Name	Jurisdiction of incorporation	Address	Telephone	Fax, website (if any) and e-mail address for primary point of

Sister owned company/ies (i.e., other companies owned by the parent company, (c) if any):

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MSG Anti-Corruption

Joint Ventures

# Management System Joint Ventures

	Jurisdiction of incorporation	Address	Telephone	Fax, websit any) and e-1 address fo primary poi
(d) Does or di	d any of these co	mpanies perforr	n services on bel	nalf of Esaote
Yes:			No:	
If yes, please ind	icate which compa	ny and the activi	ties it performs or	r performed:
Compa	ny		Activities	
If the answer aborheld:	Yes:	entify the individ	No: ual, the business a	and the position
	ve is yes, please ide	entify the individentify the individent	ual, the business a	and the position
held:	ve is yes, please ide	·	ual, the business a	
held:	ve is yes, please ide	·	ual, the business a	-
held:  Individe	ve is yes, please ide	Business entity	ual, the business a	-
BUSINESS HIS List any other agre purposes of this of the Joint Venture	ve is yes, please ide	FERENCES Venture's Partner enture's Partner vner of the Joint	thas with Esaote also includes all Venture's Partne	or had in the plegal entities in

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2.	List at least three business references (name, address, telephone, fax, e-mail address).
	Please provide references from companies with whom you have a relationship similar to
	the proposed relationship with Esaote.

Full corporate name	Name of contact person and full address	Telephone	Fax	E-mail address

3. List one or more Banking/Credit References (name, address, telephone, fax, e-mail address):

Full corporate name	Name of contact person and full address	Telephone	Fax	E-mail address

4. Percentage of Joint Venture's Partner's business which is or will be related to Esaote's business

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Joint Ventures

5.	Historical Background	_		
(a)	Number of years Joint been in the area of busi work with Esaote or on it	ness in which you will		
(b)	Briefly describe how and primary areas of busine changes, if any, of busine	ess activity, past or pro		
D.	SCOPE OF WORK			
1.	Does the Joint Venture's Pa contemplated in the Joint Ve such registration/license and required approvals.	nture's Partner Agreement	? If so, please describe	e the nature of
2.	List, if any, all employees of Joby the Joint Venture's Partner			ntities engaged
	Name	Title	Citizens	ship
3.	Please describe the experienc who will work on behalf of Es	*	Joint Venture's Par	tner personnel
4.	Are there any laws, rules, regularies Joint Venture Agreement wil			
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Joint Ventures

	may be performed by the Joint Venture's Partner or on the amount or type of compensation that may be paid for such services?
	Yes: No:
	If the answer is yes, please explain:
E.	RELATIONSHIP WITH PUBLIC OFFICIALS
1.	Does any current or former Public Official or public entity have any ownership or other interest in the Joint Venture's Partner?
	Yes: No:
	If the answer is yes, please identify the Public Official or the public entity:
2.	Is or was any Principal of the Joint Venture's Partner a Public Official or is any Principal otherwise in a position to influence or provide services for a public entity?
	Yes: No:
	If the answer is yes, please identify the Principal and the position held as Public Official:
3.	Is or was any Family Member of any Principal of the Joint Venture's Partner a Public Official? (The term "Family Member of Principal" means the Principal's spouse; the Principal's and the spouse's grandparents, parents, siblings, children, nieces, nephews, aunts, uncles, and first cousins; the spouse of any of these people, and any other
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individuals who s	snare the sam	ne nouseno	1a).				
Yes	s:		1	No:			
If the answer office, and that							
If any Principal of name of the emp or retirement from	loyer and the	e position o	or rank held? I	Please	indicate	e the dates	
Name of	Public	entity	Position or	rank	held	Date of	severan
Could any of the of a conflict of i for Esaote?							
Yes	s:		1	No:			
Would the Joint consultant or sul out under the Joi	bcontractor)	not alread	y mentioned a				
Yes	s:		Ν	Vo:			



F.

1.

2.

3.

If the answer is yes, please identify the name of the person or entity that you would rely upon and their relationship to the Joint Venture's Partner. (Note: each person or entity listed may also be required to fill out this form).
FURTHER RELEVANT INFORMATION
Does the Joint Venture's Partner have written codes, procedures or policies addressing business ethics, anti-corruption compliance, entertainment or gifts for clients or for Public Officials, or related topics? If yes, please attach.
Yes: No:
In the past 5 (five) years, has the Joint Venture's Partner (including any associated or previously associated organization or any predecessor organization), or any present or former Principal been (1) suspended from doing business in any capacity, (2) investigated for or charged with any criminal act, or (3) subject to any allegation of fraud, misrepresentation, bribery, corruption, tax evasion or other related activities?
Yes: No:
If the answer is yes, please provide complete details (on a separate sheet, if necessary):
Indicate the bank, branch, city and country to which the Joint Venture's Partner would like compensation under the Joint Venture Agreement wire transferred. (Wire transfers will be made in the Joint Venture's Partner's name, to a bank in the Joint Venture's Partner's home country or in the country in which the contractual activity will be carried out).

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Please use this space to provide any additional information which you feel may be relevant to the relationship between the Joint Venture's Partner and Esaote.

Some of the information that Esaote receives from the Joint Venture's Partner in connection with this questionnaire may include "Personal Data" defined by Section 4 of Legislative Decree June 30, 2003 no. 196 as "any information relating to natural or legal persons, bodies or associations that are or can be identified, even indirectly, by reference to any other information including a personal identification number". Furthermore, in the case in which the Joint Venture's Partner is located abroad, Esaote intends to import these Personal Data into Italy for evaluation under the Anti-Corruption Laws and the data will not be used for other purposes. For the specific purposes of such processing and transfer by Esaote, the Joint Venture's Partner will obtain prior written consent from its employees. To the extent that any Personal Data initially collected and processed by the Joint Venture's Partner but eventually transferred to Esaote pertain to third parties, the Joint Venture's Partner will duly inform these third parties of their rights under applicable data privacy laws, and obtain their unambiguous consent in writing with regards to such processing and/or subsequent transfer to Italy. By signing and completing this form and returning it to Esaote, you give your consent to the processing and use of the data for the purposes stated above.

I have reviewed this questionnaire, and I declare that the information provided is accurate and complete to the best of my knowledge and belief.

Name of the Joint Venture's Partner	Signature:
D	
Date:	Typed name and title:

Please ensure the following documents are attached (and provide English/Italian translations of documents in other languages):

Document:			
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A	Copy of company's search, incorporating document or other evidence of establishment or incorporation of the Joint Venture's Partner	1
В	Copy of required registrations or other documentation authorizing the Joint Venture's Partner to carry on the appropriate business, if required by local law	<b>↑</b>
C	Independent confirmation of ownership documentation	1
Ι	Curriculum vitae of each Principals and of each managers or executive or key employees related to the Joint Venture Agreement activity	1
E	Financial statements (audited, if available) for the prior three years, including balance sheets and profit and loss statements. If you cannot provide financial statements, please attach an explanation of why financial statements are not available	1
F	<b>Criminal records:</b> check criminal records for the Joint Venture's Partner and related entities (parent companies, subsidiaries, branches and affiliates) Principals and key management personnel or individual (if legally permissible in the country concerned)	<b>↑</b>
(	Anti-Corruption measures: procedures or policies addressing business ethics, anti-corruption compliance, entertainment or gifts for clients or Public Officials.	1

Please-return the completed Questionnaire and all attachments to the Manager.



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4	DEF.	INITION	IS	3
5	PRO	CEDURE	ES AND RESPONSIBILITIES	Errore. Il segnalibro non è definito.
	5.1	Due D	Diligence on the Intermediary	Errore. Il segnalibro non è definito.
		5.1.1	Standard Due Diligence Requirem	nentsErrore. Il segnalibro non è definito.
		5.1.2	Drafting the Note	Errore. Il segnalibro non è definito.
	5.2	Negot	iations and contents of the Intermed	diary Agreement <b>Errore. Il segnalibro non è definito.</b>
	5.3	Evalua	ntion and Decision	Errore. Il segnalibro non è definito.
6	MAN	IAGEME	ENT OF THE INTERMEDIARY A	AGREEMENTErrore. Il segnalibro non è definito.
	6.1	Choice	e of the Contract Manager	Errore. Il segnalibro non è definito.
	6.2	Duties	of the Contract Manager	Errore. Il segnalibro non è definito.
	6.3	Accou	nting records and payments	Errore. Il segnalibro non è definito.
7	CON	SULTAN	VTS	Errore. Il segnalibro non è definito.
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		7.1.1	Requesting Unit	Errore. Il segnalibro non è definito.
		7.1.2	Consultancy Approver	Errore. Il segnalibro non è definito.
		7.1.3	Procurement Function	Errore. Il segnalibro non è definito.
		7.1.4	Compliance Officer	Errore. Il segnalibro non è definito.
	7.2	Draftii	ng and approval of the Consultancy	NoteErrore. Il segnalibro non è definito.
	7.3	Assign	ment of the consultancy	Errore. Il segnalibro non è definito.
	7.4	Repor	ting activity	Errore. Il segnalibro non è definito.
8	REPO	ORTING	VIOLATIONS	Errore. Il segnalibro non è definito.
9	CON	TROLS A	AND RECORD KEEPING	Errore. Il segnalibro non è definito.
10	DISC	ZIPLINAI	RY ACTIONS	Errore. Il segnalibro non è definito.
11	MON	NITORIN	IG AND ENHANCEMETS	Errore. Il segnalibro non è definito.
12	INTE	ERIM PE	RIOD	Errore. Il segnalibro non è definito.
13	ATT	ACHME	NTS	Errore. Il segnalibro non è definito.

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Sponsorships and Donations		



#### 1 INTRODUCTION

## 1.1 Scope

This Procedure on Sponsorships and Donations (the "**Procedure**") is part of the Esaote Procedures finalized to prevent bribery-related risks, provided for under the Management System Guideline Anti-Corruption.

This procedure is intended to establish the principles of reference in relation to the development, approval and authorization of the budget relating to the donation in favor of third parties and sponsorship, as well as the process of authorization and implementation of each initiative.

In the event the sponsorships are in the scope of the Procedure "Educational Events" adopted by Esaote, rules under said Procedure are applied.

The document also aims to define the roles and responsibilities of the departments involved in the process and to determine the conditions for the transfer of information and traceability of the activities carried out.

## 1.2 Support

Details of applicable laws and Anti-Corruption Laws may change at any time, so it is important to obtain up-to-date legal advice before making any commitment on behalf of Esaote.

To this purpose must be directed to the Esaote Compliance Officer:

- questions with respect to the contents of Anti-Corruption Laws, the Code of Conduct, or any of the matters discussed in this Procedure, or their application to specific situations; and/or
- questions with respect to the financial information and internal controls provisions of the Anti- Corruption Laws, or any of the matters discussed in this Procedure, or their application to specific situations.

Should a recipient of this Procedure have doubts whether an agreement to be entered into with one party shall be ruled by this Procedure, it shall contact Esaote Compliance Officer, that shall take steps to evaluate whether the process ment submitted to its attention is subject to this Procedure.

## 2 APPLICATION

This Procedure has been reviewed and approved by the Board of Directors of Esaote S.p.A.; its

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adoption and enforcement is mandatory for Esaote S.p.A. and all its Subsidiaries.

Moreover, Esaote will also use its influence, to the extent reasonable under the circumstances, to cause companies and entities in which Esaote has a non-controlling interest and business partners to meet the standards set up in this Procedure by adopting and maintaining an adequate system of internal controls consistent with the requirements established by the Anti-Corruption Laws. In any case, the representatives indicated by Esaote in such companies and entities shall use their best efforts to cause the standards set up in this Procedure to be adopted.

Relevant circumstances include the degree of Esaote ownership of the company or entity (e.g. joint venture, consortia) and the laws and regulations governing the business operations in the country in which the company or entity is located or the activities are based.

### 3 REFERENCE

- Code of Conduct;
- Model;
- "Management System Guideline Anti-Corruption".

### 4 DEFINITIONS

When used in this Procedure, the following terms have the meanings set forth below:

**ANTI-CORRUPTION LAWS**: the Italian Criminal Code, the Legislative Decree 231 and other applicable provisions, the FCPA, the UK Bribery Act, other public and commercial anti-bribery laws in effect around the world, and international anti-corruption treaties such as the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions, and the United Nations Convention against Corruption.

**CODE OF CONDUCT**: Esaote's Code of Conduct.

**ESAOTE**: Esaote S.p.A. and its Subsidiaries.

**COMPLIANCE OFFICER**: A resource within the Company entrusted with the management and implementation of policies aimed at avoiding or reducing the exposure to liability for any violation of national or international regulations, decisions of competent authorities or other applicable rules of conduct. The Esaote Compliance Officer: (i) ensures knowledge of applicable regulations; (ii) makes proposals, preparation and update of compliance policies for preventing any corporate conduct that may be contrary to regulations; (iii) acts as reference person for Group companies; (iii) reports on the

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implementation and monitoring of compliance policies to the Board of Directors; (iv) assists the 231 Supervisory Body in relation to any Legislative Decree 231 issue; and (v) carries out communication and training on compliance policies.

**ESAOTE PERSONNEL**: the directors, officers, members of corporate bodies, managers and employees of Esaote.

**HUMAN RESOURCES DEPARTMENT:** The human resources department of Esaote S.p.A.

**INTERNAL AUDIT:** If appointed, a professional or a company appointed by Esaote S.p.A. responsible for the examination and independent evaluation of the internal control system, in order to verify the compliance with the requirements of the Management System Guideline Anti-Corruption, on the basis of its periodical audit plan approved by the Board of Directors of Esaote S.p.A..

**LEGISLATIVE DECREE 231**: Italian Legislative Decree June 8, 2001, No. 231, as amended from time to time.

**MANAGER:** The most senior manager of the department, of the area or of the operative company requiring the Intermediary services.

**MANAGEMENT SYSTEM GUIDELINE ANTI-CORRUPTION:** Esaote's Management System Guideline Anti-Corruption approved by the Board of Directors of Esaote S.p.A.

**MODEL 231**: the Model concerning the organization, management and controlling activities of Esaote (ex Legislative Decree 231 of 2001) approved by the Board of Directors of Esaote S.p.A..

**BENEFICIARY**: Person who enjoys the effects or benefits of the donation.

**SPONSEE**: party that enters into a Sponsorship Agreement with Esaote.

**SPONSORSHIPS**: promotional and advertising communications initiatives through which a subject called "sponsee", agrees to associate, against payment, to its business the name or distinguishing sign of the "sponsor" in order to promote a positive image, identity, brand or its products / services

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**SUBSIDIARY**: any entity that is directly or indirectly controlled by Esaote S.p.A.(1) in Italy and abroad.

**TOP MANAGEMENT**: apical position of the company (e.g. Managing Director, General Manager, Chairman, Executive Officers).

**231 SUPERVISORY BODY:** the supervisory body (*Organismo di Vigilanza*) of Esaote S.p.A., as defined in Esaote Organizational Model and appointed pursuant to the Legislative Decree 231.

### 5 RESPONSIBILITIES

## 5.1 Responsibilities of Esaote

Human Resources Function carries out the preliminary assessment of each initiative identified prior to the approval of the Chief Executive Officer (CEO) of Esaote.

#### 5.1.1 Public Relation Function

The Public Relations Function has the following responsibilities:

• Ensure the collection of the estimates of expenditure (budget) relating to donations and sponsorships from Esaote Subsidiaries and ensure the identification of the same for Esaote

## 5.1.2 Role of the Compliance Officer

The Compliance Officer shall evaluate the results of the due diligence conducted in connection with the beneficiaries / sponsored as provided for in par. 6 of this Procedure which incorporates the requirements of the Anti -Corruption Guidelines Management System, or, if there are specific "Red - Flags", suggest conducting any further and appropriate activities.

## 5.1.3 Corporate Function

Corporate Function shall provide support to the Public Relation Function in the definition of the expenditure forecasts for Donations and Sponsorships and in the evaluation of proposals for Donations received from the Subsidiaries shall ensure a timely flow of information to the Human Resources Department in relation to the implementation of each initiative involving a Donation or a sponsorship.

(1) The list of these companies is that included in the appendix "Controlled subsidiaries" of the most recent approved consolidated financial statement.

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## 5.2 Responsibilities of Subsidiaries

The Subsidiaries of Esaote ensure the definition of the expenditure forecasts for donations and sponsorships, as well as the identification of information about each initiative, ensuring the transmission to Public Relations function through the Area Manager or senior management of the company.

## 6 CRITERIA FOR THE IDENTIFICATION OF THE RECIPIENTS OF DONATIONS AND SPONSORSHIPS

The choice of the recipients of donations and sponsorships must take into account the principles of ethics and transparency and must be able to contribute to the improvement of the image of Esaote.

Since these payments are a vehicle of the image of the company and have an effect in terms of reputation should not be construed as a mere response to exigent circumstances, but as punctual interventions defined on the basis of a careful assessment of the bodies/ associations and proponents of expected effectiveness of the proposed interventions.

### 7 DESCRIPTION OF ACTIVITIES

### 7.1 Definition and budget approval of donations and sponsorships

The Public Relations function, requires on an annual basis to the first-level managers under the executive officers of Esaote (CEO and Chairman), and to the top management of the Subsidiaries forecast of expenditure relating to the Donations planned for the following year (budget) as well as the related sponsorship activities for the same period.

The Public Relations Function processes the total budget of Donations and Sponsorships aggregating the data defined for Esaote with those received from Subsidiaries and asking any further clarification relating to information and data received.

The total budget is then submitted for approval to the Chief Executive Officer of Esaote S.p.A.

Following approval of the Budget Esaote and Subsidiaries ensure the inclusion of the figures for donations on a special account "Donations" and in a specific line of the relevant budget.

Regarding Sponsorships Esaote and Subsidiaries ensure the inclusion of the amounts approved on the contract to which they refer, in the relevant budget.

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The contributions related to the Donations and Sponsorships are always paid by the Company which has identified them and therefore includes them in its overall budget that follows the normal procedure of approval and authorization.

## 7.2 Approval of donations and sponsorships

The implementation of each initiative envisaged in the budget must be communicated in advance by the senior management of subsidiaries, and top-level managers under the executive officers of Esaote SpA (Chairman and CEO), to the Public Relations Function, together with a summary sheet describing the activity.

The Public Relations Function, makes a preliminary assessment of the initiatives reported.

## 7.3 Anti corruption due diligence on the beneficiaries and sponsee

### 7.3.1 Beneficiaries of Donations:

Beneficiaries of the Donations and sponsorships must be subjected to a process of due diligence conducted in accordance with the instructions contained in the par . 5.1 of the Procedure on Intermediaries and Consultants and in accordance with the following provisions of 6.3.2

## 7.3.2 Due Diligence.

The entity requesting the Donation/Sponsorship, before sending the data and information contained in the summary sheet to the Public Relations Function, will have to submit to the evaluation of the Compliance Officer with a note the results of the due diligence and attach the documents that prove, if required by law:

- the existence and registration of the Beneficiary/Sponsee by the competent authority (e.g. registration with the Chamber of Commerce office or equivalent);
- the Beneficiary/Sponsee is in possession of the necessary requirements to carry out the object of the donation/sponsorship (e.g. Ministerial authorization, permission of the competent authority);
- the exercise of the activity in the last 3 years (e.g. Financial Statements).

The Compliance Officer shall also verify, based on the information provided by the applicant in the above note on the due diligence, as well as the sponsorship agreement or request for donation, that have been included specific provisions pursuant to which:

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- payments to the Beneficiary/Sponsee are made solely on account registered in the name of
  the same and that no payment is made in cash or numbered accounts, or to a person other
  than the beneficiary or to a third country other than the country of the Beneficiary/ Sponsee
  or one in which the activities covered by the authorization will take place;
- payments to the Beneficiary/Sponsee are recorded in the books fairly and transparently.

## 7.4 Approval of Donations and sponsorships

The applicant, once received the feedback from the Compliance Officer on the results of the due diligence, submit the said document together with the summary sheet on the initiative to the Public Relations Function for authorization.

The Public Relations Function communicates to senior management of the Subsidiaries, and top-level managers under the executive officers of Esaote SpA (Chairman and CEO), the outcome of the due diligence, which analyzes the content of each individual initiative and assesses the coherence within the group.

In the event of a negative response the Public Relations Function communicate the reasons for the decision.

## 7.5 APPROVAL OF DONATIONS AND SPONSORSHIPS NOT PROVIDED A BUDGET

Proposals in excess of the estimates of expenditure included in the budget are generally not permitted.

In very exceptional cases may be evaluated if they are accompanied only by the summary sheet, including a note explaining the reasons for which the payment or sponsorship cannot be deferred. The authorization process remains unchanged.

### 7.6 NEGOTIATING AND CONTRACTING OF SPONSORSHIP AGREEMENTS

For sponsorship requests that have passed the approval process, the applicant shall contact the potential Sponsee that promotes or organizes the sponsor activity / event in order to define the Sponsorship Agreement.

In the Sponsorship Agreement are indicated therein the description of the event/initiative, the benefits for Esaote, the amount of the sum due and the payment method.

The text of the Agreement shall also contain:

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- the declaration of the amount paid is sponsored exclusively the consideration for the service
  provided for in the Sponsorship Agreement and that these sums will never be forwarded to
  a Public Official to bribe or transferred, directly or indirectly, to members of the corporate
  bodies, directors, of Esaote or its employees;
- the declaration of the Sponsee that at the time of signing the Sponsorship Agreement and during its execution the company or its owners, directors or employees are or will be Public Officials
- the currency and the amount to be paid under the Sponsorship Agreement;
- the terms of billing and the terms of payment, taking into account that such payments can only be made in favor of the Sponsee and in the country of establishment of the Sponsee (or the country in which the activities covered by the authorization will take place), exclusively in favor of the registered Sponsee as indicated in the sponsorship Agreement and never on numbered accounts or in cash;
- the commitment of the sponsored to comply with applicable laws, the anti-corruption laws
  and the provisions of this procedure, and to record in its books and records fairly and
  transparently the amount received;
- the clause "Administrative Responsibility" with the explicit right to terminate the contract of Esaote, to stop payments and receive compensation for damages in case of breach by the Sponsee of its obligations, representations and warranties as above, or in the case of violation of anti-corruption laws or this procedure (see the Procedures on Standard Contractual Clauses);
- The right of Esaote to carry out audits on the Sponsee in the event that has a reasonable suspicion that the Sponsee may have violated the provisions of this Procedure and/or the Sponsorship Agreement.

Any request for modification / clarification of the terms included in the list mentioned above must be forwarded to the Compliance Officer of Esaote that must give its opinion about it.

A copy of the contract must be submitted to the Public Relations Function.

### 7.7 Management of sponsorship agreements

Function applicant (the "Contract Manager") is the manager of sponsorship contracts entered into and monitors the proper execution of the Sponsorship Agreement, with the cooperation of the Public Relations function. In particular, it checks that the Agreement is fully observed.

The payment takes place only as indicated in the Sponsorship Agreement, subject to verification that the contract was actually executed.

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### 8 REPORTING VIOLATIONS

Any suspected or known violation of the Anti-Corruption Laws and of this Procedure must be reported immediately to one or more of the following:

- the employee's direct supervisor or, in case of violation on the part of the Intermediary, the Contract Manager;
- the Audit and Compliance Committee;
- the Esaote Compliance Officer;
- the 231 Supervisory Body;
- in any case, through the dedicated channels indicated in the Esaote Procedure on Ordinary Reporting and Confidential Reporting ("whistleblowing").

The direct supervisor, the Esaote Compliance Officer and the relevant Human Resources Department will consult to identify the course of action, including the application of disciplinary measures as appropriate.

#### 9 CONTROLS AND RECORD KEEPING

Esaote Internal Audit will independently review and evaluate internal controls to help verifying compliance with the requirements of this Procedure, on the basis of its periodical program approved by the Board of Directors of Esaote S.p.A..

The original documentation related to the selection and approval of the Intermediary, the Intermediary Agreements and the controls of compliance with this Procedure is to be saved for 10 years as follows:

- for the Subsidiaries where a Esaote Compliance Officer is present: by the relevant Esaote Compliance Officer;
- for the other Subsidiaries: by the relevant Financial Officer.

### 10 DISCIPLINARY ACTIONS

Esaote shall use every reasonable effort in order to prevent any conduct in violation of Anti-Corruption Laws and/or this Procedure and interrupt and sanction any conduct to the contrary of Esaote Personnel.

Esaote will take appropriate disciplinary action according to the Model and the collective employment agreements or other applicable national regulations, against any Esaote Personnel (i)

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whose actions are found to violate Anti-Corruption Laws or this Procedure, (ii) who unreasonably fail to detect or fail to report any violations according to the Management System Guideline Anti-Corruption or who retaliate against others who report such violations. Disciplinary action may include the immediate termination of employment.

### 11 MONITORING AND ENHANCEMETS

The Esaote Compliance Officer is responsible for oversight of this Procedure.

The Esaote Compliance Officer must periodically review this Procedure to ensure that it remains effective. In addition, the business units, Contract Manager(s), Compliance and Audit Committee, Internal Audit and the company's independent auditors should recommend enhancements to the Procedure if gaps or weaknesses are identified, and as emerging "best practices" develop.

If a violation is found, the Esaote Compliance Officer will determine whether Procedure revisions or procedural enhancements would help prevent recurrence of the violation.

**Key Opinion Leaders** 

## **Key Opinion Leaders - Guidelines**



**Key Opinion Leaders** 

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# 1. Purpose

The aim of this Guidelines is to describe how:

- the Esaote's Corporate Functions, namely Global Marketing (GMKT), Research & Developments (RD), and Esaote's Local Entities (LE) manage the overall KOLs activities relevant to product/technology/educational/promotion/clinical activities of the existing product lines and new products worldwide, both in human and veterinary application fields in Ultrasound (US) and MRI;
- the Esaote's Corporate Functions, namely Medical Affairs (MA), manage the overall KOLs activities relevant to post market surveillance/clinical evaluation processes apply to US and MRI devices intended for human use only;
- Esaote Corporate Governance, Legal and Compliance Functions as well as Group Compliance
  Officer support Corporate Functions and LE to manage legal and compliance risks in dealing
  with HCPS and HCOS.
- the Esaote's Local Entities (LE) manage the overall KOLs activities relevant to educational/promotion/clinical activities of the existing product lines and new products worldwide, both in human and veterinary application fields in Ultrasound (US) and MRI;

This Guidelines are intended to provide indications on how to manage in a transparent a clear way the relationship with Healthcare Professionals (HCPs) and/or Healthcare Organizations (HCOs) thus reinforcing Esaote commitment to endorse and apply the best industry practices to promote our ethical dealings in the Healthcare industry.

Besides that, when specifically dealing with clinical investigation and/or clinical-related activities involving human subjects, these activities has to be conducted taking care to respect both international standards (ISO 14155, Declaration of Helsinki) and local binding laws (e.g. GDPR, HIPPA) that, in general terms, are intended to:

- protect the rights, safety and well-being of human subjects involved;
- ensure the scientific conduct of the clinical investigation and credibility of the clinical investigation results;
- define clearly the responsibilities of all the actors involved in the process

# 2. Applicability

These Guidelines apply to all Functions (FA) that are in contact with Key Opinion Leaders (KOLs) for clinical-related activities relevant to the medical devices manufactured by Esaote.

# 3. References

- World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, revision October 2013;
- ESAOTE CODE OF CONDUCT, 2016;
- MedTech Europe Code of Ethical Business Practice 2018;
- ASSOBIOMEDICA CODE OF ETHICS;
- COCIR Code of Conduct 2018:
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and successive amendments [Annex II 3.1 and Annex X 1.1c];



- MEDDEV 2.7/1 revision 4 Clinical Evaluation: A Guide For Manufacturers And Notified Bodies Under Directives 93/42/EEC And 90/385/EEC;
- MEDDEV 2.12/1 Guidelines on a medical devices vigilance system;
- MEDDEV 2.12/2 Guidelines on post market clinical follow-up studies: a guide for manufacturer and notified body;
- UNI EN ISO 14155:2012 Clinical Investigation of medical devices for human subjects Good clinical practice and other binding national regulations and applicable laws in the states where a clinical investigation is going to be initiated by Esaote;
- EN ISO 13485:2016 / EN ISO 13485:2012 Medical devices Quality management systems Requirements for regulatory purposes [sections 3.12, 7.2.3 and 8.2.1];
- Italian D. Lgs. 231/01 and any other applicable anti-bribery regulations.

# 3.1. Referenced documents

- Organizational Model under Italian D. Lgs. 231/01
- QOP000011 Product Validation
- QOP000015 Post-Market Surveillance
- QOP000021 Clinical Evaluation Procedure
- QOP000022 Marketing Procedure
- Corporate Identity Guidelines
- Social Media Guidelines

# 3.2. Used abbreviations

Abbreviation	Meaning
AS	GMKT Application Specialist (US)
CEO	Chief Executive Officer
coo	Chief Operating Officer
CLGCO	Chief Legal, Governance & Group Compliance Officer
CQO	Chief Quality Officer
CRO	Contract Research Organization
СТО	Chief Technology Officer
EDM	Educational Marketing (MRI)
EIT	Esaote-Initiated Trial
FA	Company Function (generic)
FV	Sales
GMKT	Global Marketing
НСО	Healthcare Organization
НСР	Healthcare Professional



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Abbreviation	Meaning
HOF	Head of Function
IIT	Investigator-Initiated Trial
KOL	Key Opinion Leader
LA	Legal Affairs
LAS	Local Application Specialist
LCM	Local Country Manager
LE	Local Entities
LMKT	Local Marketing
LSD	RD Lead System Designer
LSM	RD Lead Scrum Master
MA	Medical Affairs
MAL	Medical Affairs Leader
MKT	Marketing
MM	Marketing Manager
МО	Marketing Operations
MRI	Magnetic Resonance Imaging
MRI GMM	MRI Global Marketing Manager
NA	Not Applicable
OPL	Operations Leader
PL	RD Project Leader
РМ	RD Program Manager
PMCF	Post-Market Clinical Follow-Up
РММ	GMKT Product Marketing Manager
PMS	Post-Market Surveillance
PMSCF	Post-Market Surveillance Clinical Follow Up
RA	Regulatory Affairs
QA	Quality Affairs
QAL	Quality Assurance Leader
RBD	Regional Business Director
RD	Research & Development
SYSM	System Manager (MRI)
SYS_ADI	System Application Design & Integration (US)



Abbreviation	Meaning
US	Ultrasound & Probes
US GMM	US Global Marketing Manager

# 3.3. Definitions

## **Contract Research Organization (CRO)**

Person or organization contracted by the sponsor to perform one or more of the sponsor's clinical investigation-related duties and functions.

[UNI EN ISO 14155:2012]

# **Clinical Investigation**

Systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device.

Note: 'clinical trial' or ' clinical study' are synonymous with ' clinical investigation'. [MEDDEV 2.7/1 revision 4]

### **Clinical Performance**

Behavior of a medical device or response of the subject(s) to that medical device in relation to its intended use, when correctly applied to appropriate subject(s). [MEDDEV 2.7/1 revision 4]

### **Clinical Safety**

Freedom from unacceptable clinical risks, when using the device according to the manufacturer's Instructions for Use. [MEDDEV 2.7/1 revision 4]

### **Conformity Assessment**

The systematic examination of evidence generated, and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Requirements.

[GHTF/SG1/N78:2012]

## **Esaote-Initiated Trial**

Clinical investigation with scientific and medical merit developed and sponsored by Esaote to assess the safety or performance of a medical device/function. The sponsor is responsible for the legal and regulatory responsibilities of the clinical investigation and for the conduct and management of the study as defined by all applicable local laws and regulations.

### **Expected Service Life**

Time period defined by the manufacturer during which the medical electrical equipment or medical electrical system is expected to remain suitable for its intended use. [IEC 60601-1 Ed.3.1]

## **Group Company or Company**

Includes Esaote S.p.A. and any Company in Esaote Group.



## **Healthcare Organizations (HCO)**

Healthcare Organizations are intended to be medical, scientific and research institutions, such as hospitals, private clinics and medical offices, universities.

Center that provides health services such as diagnosis of diseases, surgical operations, treatment and recovery of patients. They may also perform research and teaching activities. [Code of Ethics, Assobiomedica 2018]

]MedTech Europe Code of Ethical Business Practice 2018] [COCIR Code of Conduct 2018]

# **Healthcare Professionals (HCP)**

Healthcare Professionals are intended to be persons associated with either a specialty or a discipline, and who are qualified and allowed by regulatory bodies to provide a healthcare service to a patient, such as a medical doctor, a technologist, a physician, a sonographer, an engineer.

[Code of Ethics, Assobiomedica February 2018]

# **Investigator-Initiated Trial**

Clinical investigation with scientific and medical merit, developed and sponsored by an independent investigator like individual investigators or an academic sponsor like institutions, collaborative study groups and cooperative groups. An IIT is clinical or non-clinical study conducted for which the IIT sponsor requests Esaote to provide either funding, medical device products or both. The sponsor is responsible for the legal and regulatory responsibilities of the clinical investigation and for the conduct and management of the study as defined by all applicable local laws and regulations.

## **Key Opinion Leader (KOL)**

An experienced and independent Healthcare Professional that can provide valuable third-party opinions and advices on product's performances and quality as well indications on present and future specific customer needs.

### Local Entities (LE)

Local marketing, local application specialists, and local sales.

Local sales include Local Country Manager in case of subsidiary, and Regional Business Director in case of indirect operations.

### Post-market clinical follow-up study

A study carried out following the CE marking of a device and intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a device when used in accordance with its approved labelling.

[MEDDEV 2.12/2 rev.2]

### Post-market surveillance

Systematic process to collect and analyse experience gained from medical devices that have been placed on the market.

[ISO 13485:2016]

### Sponsor

Individual or organization taking responsibilities <u>and liability</u> for the initiation or implementation of a clinical investigation.

[UNI EN ISO 14155:2012]



#### Responsibilities 4.

The responsibility of participation by the various roles defined in these Guidelines is defined according the RACI (Responsible, Accountable, Consulted, Informed) matrix. It clarifies the roles and responsibilities. When the Accountable is the superior of the Responsible is not indicated in the table.

### **RACI Definitions:**

R	<u>R</u> esponsible	The person who is <u>assigned</u> to do the work
A Accountable The person who makes the <u>final decision</u> and has the <u>ultimate</u> <u>ownership</u>		
С	<u>C</u> onsulted	The person who must be consulted <u>before</u> a decision or action is taken
I	<u>I</u> nformed	The person who must be informed that a decision or action <u>has</u> been taken

Below are main roles and responsibilities addressed within this Guidelines.

Role	Responsibility
PMM/AS/EDM/US GMM/MRI GMM (GMKT)	<ul> <li>management of the product external evaluation and knowledge transfer</li> <li>marketing activities in view of new products and/or existing product updates/releases</li> <li>educational activity on existing/new products/releases and clinical topics</li> <li>customer's visit management</li> <li>technical/clinical content collection (e.g. clinical images/clips, white papers, eBooks, posters, APPs/libraries, publications/articles/videos, social media posts, and similar)</li> <li>KOL management for exhibition booth/workshops/events/meetings</li> </ul>
LCM/RBD/LMKT/LAS (Local entities)	<ul> <li>support to product external evaluation and knowledge transfer</li> <li>marketing activities in view of new products and/or existing product updates/releases</li> <li>educational activity on existing/new products/releases and clinical topics</li> <li>customer's visit management</li> <li>technical/clinical content collection (e.g. clinical images/clips, white papers, eBooks, posters, APPs/libraries, publications/articles/videos, social media posts, and similar)</li> <li>KOL management for exhibition booth/workshops/events/meetings</li> </ul>
SYSM/SYS_ADI/PM/PL (RD)	product feature/technology development in cooperation with KOL
MA	Coordination and management of Post-market surveillance activities including new clinical data collection on newly introduced and already existing product and, when applicable, of Pre-market clinical trial ahead of a new products release



<ul> <li>CLGCO</li> <li>Support to Corporate Functions and LE to manage legal and compliance risks in dealing with HCPS and HCOS</li> </ul>
---

# 5. Policies and controls

# **5.1.** General Principles

The interaction between all Group Companies and Healthcare Professionals/Healthcare Organisations is an important feature in achieving Esaote objectives to make safe, innovative and reliable technology and related services available to more people. The development of innovative medical devices and technologies and the improvement of products require collaboration with Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services. The safe and effective use of medical technology and related services requires to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support. The support of medical research and education serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction all Group Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the relationship.

For such purpose, the following **ten general principles** must always be abided in any case of interaction with Healthcare Professionals/Healthcare Organisations:

- **1.** All the interactions must be transparent and comply with national and local laws, regulations or professional codes of conduct.
- **2.** Interaction with Healthcare Professionals/Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Esaote products.
- **3.** All the materials and information shared with Healthcare Professionals/Healthcare Organisations must be accurate, balanced, fair, objective, complete, not misleading and be substantiated by the appropriate evidence.
- **4.** Never provide, offer or promise anything of value to improperly influence a decision affecting any of Esaote business, including any decision regarding the purchase and supply of Esaote products. Anything provided of value must be given without expectation of reciprocity, explicit or implied obligation, favour, or action in return.
- **5.** Always consider and resolve any potential conflict of interest which has been identified in interactions with Healthcare Professionals/Healthcare Organisations. A conflict is any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision.
- **6.** There must always be a real, genuine and legitimate business need for our interactions with Healthcare Professionals/Healthcare Organisations.
- **7.** Anything provided of value must be appropriate in the circumstances, be reasonable in value when measured by local market conditions and must be infrequent when combined with all types of benefits (for example, fees for service and hospitality) provided cumulatively. The assessment of whether the benefits are infrequent, must be made on a case by case basis. To determine frequency, we need to assess whether the additional benefit (when combined with all previous benefits provided, usually within a 12 month period) might undermine the independence, and/or improperly



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influence the decision making, of the recipient for the benefit of our business. Any fee for service must not exceed the fair market value of the services provided.

- **8.** Anything provided of value must be given openly and transparently and must be accurately recorded in Esaote books and records. It must be provided in a manner that would not result in adverse reputational impact or embarrassment to Esaote if publicly disclosed.
- **9.** All payments to Healthcare Professionals/Healthcare Organisations must be publicly disclosed where required under applicable law and industry standard to which we adhere.
- **10.** For interactions with Healthcare Professionals/Healthcare Organisations, such as where services are performed by a Healthcare Professional for Esaote or on behalf of Esaote, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by Esaote.

As regards to Italy, all the marketing activities, such as congresses, seminars, and training events are in compliance with the Esaote "Model of Organization, Management and Control under Legislative Decree n. 231/01 - Annex 2.3".

# 5.2. Rules on specific agreements

In addition to the above general principles, all Group Companies must always apply comply with the following rules in respect of the types of interactions with Healthcare Professionals/Healthcare Organizations.

# 1) Engagements of Healthcare Professionals

We may engage Healthcare Professionals as consultants and advisors to provide bona fide consulting and other services as contemplated in these Guidelines. We may pay Healthcare Professionals reasonable remuneration for performing these services. In all cases, arrangements must be permitted under the laws and regulations of the country where the Healthcare Professional is licensed to practice and be consistent with applicable professional codes of conduct in that country.

Arrangements shall not be contingent in any way on the prospective Healthcare Professional's past, present or potential future purchase, lease, recommendation, prescription, use, supply or procurement of our products or services.

In addition to the general principles above, the arrangements which cover consultancy or other services to be provided by a Healthcare Professional must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

- (i) arrangements must be entered into only where a legitimate business need for the services is identified in advance;
- (ii) the number of Healthcare Professionals retained for consultancy or other services must not be greater than the number reasonably necessary to achieve the identified need:
- (iii) selection of Healthcare Professionals must be based on criteria directly related to the identified business need and the relevance of the consultant's qualifications, expertise and experience to address the identified need. The volume or value of business generated by the individual or the Healthcare Organization where s/he performs her/his professional activity is not a relevant criterion;
- (iv) arrangements with Healthcare Professionals must be documented in a written agreement, signed by the parties in advance of the commencement of the services,



- which must specify the nature of the services to be provided and the basis for payment for those services;
- (v) the Esaote Group Company which executes the Contract with the HCP/HCO maintains records of the services, and associated work products (if any), provided by the Healthcare Professionals and of the use made of those services;
- (vi) any hospitality provided to the HCP must be secondary to the purpose of the engagement. The hospitality and venue location used must be appropriate to the services being provided, not susceptible to be qualified as "resort like" or luxurious and reasonable in value (taking into account the location of the hospitality);
- (vii) all fees paid must not exceed the fair market value of what is appropriate and reasonable in value (taking into account the HCP's main country of work);
- (viii) all payments made for services must comply with all applicable tax and other legal requirements;
- (ix) the written agreement must detail which expenses can be claimed by the HCP in relation to the provision of the services and the basis for payment of these by the Esaote Group Company;
- (x) when selecting an HCP for consultancy or other services, it must be considered whether the selection is proportionate and appropriate in the context of the value of any benefits (which include financial payments for service fees or other benefit inkind) the individual has already received from the Esaote Group Company within the last 12 months.

In Italy, all the marketing activities that include the management of commercial collaboration and research contracts must also comply with the requirements set forth in the Esaote "Model of Organization, Management and Control" under Legislative Decree n. 231/01 - Annex 2.8".

## 2) Loan for use of Company's products

A Company may grant the use at no charge of its own products to Healthcare Professionals and Healthcare Organizations for legitimate purposes (e.g. education, demonstration, test, users' feedback, research and similar). These purposes include without limitation enabling Healthcare Professionals and Healthcare Organizations to evaluate and/or familiarize themselves with the safe, effective and appropriate use and functionality of the product and/or related service and to determine whether, or when, to use, order, purchase, prescribe or recommend the product and/or service in the future.

Provision of products must not improperly reward, induce and/or encourage Healthcare Professionals and Healthcare Organizations to purchase, lease, recommend, prescribe, use, supply or procure our products or services.

The Esaote Group Company in all cases maintains appropriate records in relation to the provision of products, including proof of delivery when returning products.

Provision of products to Healthcare Professionals and Healthcare Organizations must be documented in a written agreement, signed by the parties in advance, which must specify the products to be delivered, the purpose of the provision, a defined period of time appropriate to the purpose and any limitation to the use of the products.

In Italy, all the marketing activities that include the management of the loan for use leases must also comply with the requirements set forth in the Esaote "Model of Organization, Management and Control under Legislative Decree n. 231/01 - Annex 2.2".



# 5.3. Controls

The activities envisaged by the agreements under these Guidelines must be substantiated and evidenced by activity reports.

Before making any payment of fees for services the Group Company performs a documented assessment of whether the services were properly carried out according to the agreement and the relevant fees are actually due. The Group Company implements a separation of duties, so that personnel who propose and/or approve the agreement are different from those performing the assessment of the services carried out and the relevant fees accrued.

Adequate documentation, including without limitation the agreement, related reports and invoices, statements, disclosures and approvals under Paragraph 5.4, must be retained by the Local entity for a reasonable period of time.

# **5.4.** Statements, Disclosure and Approvals

Before entering into the agreements under Paragraph 5.2 the Group Company collects from any Healthcare Professional involved a statement confirming the absence of conflict of interest.

The Group Company maintains appropriate transparency by requiring prior written notification to the Healthcare Organization, the Healthcare Professional's superior or other locally-designated competent authority (if any), fully disclosing the purpose and scope of the agreements under Paragraph 5.2.

All required consents and approvals requested by applicable laws (if any) must be obtained before entering into the agreements, including from the Healthcare Organization administration or from the Healthcare Professional's superior (or locally-designated competent authority), as applicable.

# 6. Process operations

All the interactions with Healthcare Professionals and Healthcare Organizations included in the following paragraphs of this Section 6, and any relevant activity, shall be conducted in compliance with the Policies and Controls specified in Section 5 and in accordance with the process requirements described below.

# **6.1.** Collaboration (and Loan for Use) Agreement: Marketing & Healthcare Organization - GMKT Activities and Actions

This section provides the detailed process operations relevant to the KOLs activities represented by a **Healthcare Organization** (HCO) in cooperation with GMKT worldwide both in human and veterinary application fields in US and dedicated MRI.

The present process applies both to new products and installed base.



- **6.1 Section A**: it is focused on the <u>collection of marketing material</u> (e.g. clinical images/clips, white papers, eBooks, posters, APPs/libraries, publications/articles/videos, social media posts, and similar), the execution of educational plans and customer's visits.
- **6.1 Section B**: it is focused on the <u>product external evaluation</u> to be conducted on-site in order to receive the KOL's feedbacks upon the overall product performances and its potential future improvements. This activity might include the free loan of use option relevant to products/parts under external evaluation, refer to Collaboration (and Loan for Use) Agreement with HCO for Marketing Objectives. The GMKT documentation is intended to be created following to the KOL activities.

Step	Activity	Document in- out / Transaction	R	А	С	I
	6.1 - Section A					
1A	GMKT identifies the KOL (Healthcare Organization) and relevant activities according to the marketing needs for both human and veterinary topics in US and MRI	-	GMKT	-	US GMM and/or MRI GMM, PMM, EDM, LMKT	LCM, RBD, FV, FA
2A	GMKT prepares the KOL contract according to the standard agreement for both human and veterinary topics in US and MRI	MKT Healthcare Organization	GMKT	-	US GMM and/or MRI GMM, PMM, EDM, LA	LCM, RBD, FA
3A	Contract terms review	Final Contract Doc.	GMKT	LA	PMM, US GMM and/or MRI GMM	-
4A	Contract Signature	Contract Signed	US GMM and/or MRI GMM	GMKT	-	LA, PMM



Step	Activity	Document in- out / Transaction	R	Α	С	I
5A	GMKT executes contract terms till the final contract expiration		GMKT	-	PMM, EDM, LMKT, LAS	LCM, RBD, US GMM and/or MRI GMM, FA
	6.1 - Section B					
1B	PMM identifies the KOL ( <b>Healthcare Organization</b> ) according to the external evaluation needs for both human and veterinary topics in US and MRI	-	PMM	-	US GMM and/or MRI GMM, EDM, GMKT, LCM, RBD, LMKT	LCM, RBD, FV, FA
2B	PMM prepares the KOL contract according to the standard agreement for both human and veterinary topics in US and MRI	MKT Healthcare Organization	PMM	-	US GMM and/or MRI GMM, EDM, GMKT, LA, MA	-
3В	Contract terms review	Final Contract Doc.	PMM	LA	GMKT, US GMM and/or MRI GMM	-
4B	Contract Signature	Contract Signed	US GMM and/or MRI GMM	PMM	-	LA, GMKT



Step	Activity	Document in- out / Transaction	R	A	С	I
5B	PMM executes contract terms till the final contract expiration		PMM	-	GMKT, LMKT, LAS	US GMM and/or MRI GMM, LCM, RBD, FA



# **6.2.** Collaboration (and Loan for Use) Agreement: Marketing & Healthcare Professional - GMKT Activities and Actions

This section provides the detailed process operations relevant to the KOLs activities represented by a **Healthcare Professional (HCP)** in cooperation with GMKT both in human and veterinary application fields in US and dedicated MRI.

The present process applies both to new products and installed base.

- **6.2 Section A**: it is focused on the collection of <u>marketing material</u> (e.g. clinical images/clips, white papers, eBooks, posters, APPs/libraries, publications/articles/videos, social media posts, and similar), the execution of educational plans and customer's visits.
- **6.2 Section B**: it is focused on the <u>product external evaluation</u> to be conducted on-site in order to receive the KOL's feedbacks upon the overall product performances and its potential future improvements. This activity might include the free loan of use option relevant to products/parts under external evaluation, refer to Collaboration (and Loan for Use) Agreement with HCP for Marketing. The GMKT documentation is intended to be created following to the KOL activities.

Step	Activity	Document in- out / Transaction	R	A	С	I
	6.2 - Section A					
1A	GMKT identifies the KOL (Healthcare Professional) and relevant activities according to the marketing needs for both human and veterinary topics in US and MRI	-	GMKT	-	US GMM and/or MRI GMM, PMM, EDM, LMKT	LCM, RBD, FV, FA
2A	GMKT prepares the KOL contract according to the standard agreement for both human and veterinary topics in US and MRI	MKT Healthcare Professional	GMKT	-	US GMM and/or MRI GMM, PMM, EDM, LA	LCM, RBD, FA



Step	Activity	Document in- out / Transaction	R	А	С	I
3A	Contract terms review	Final Contract Doc.	GMKT	LA	PMM, US GMM and/or MRI GMM	-
4A	Contract Signature	Contract Signed	US GMM and/or MRI GMM	GMKT	-	LA, PMM
5A	GMKT executes contract terms till the final contract expiration		GMKT	-	PMM, EDM, LMKT, LAS	US GMM and/or MRI GMM, LCM, RBD, FA
	6.2 - Section B					
1B	PMM identifies the KOL ( <b>Healthcare Professional</b> ) and relevant activities according to the external evaluation needs for both human and veterinary topics in US and MRI	-	PMM	-	US GMM and/or MRI GMM, EDM, GMKT, LCM, RBD, LMKT	LCM, RBD, FV, FA
2B	PMM prepares the KOL contract according to the standard agreement for both human and veterinary topics in US and MRI	MKT Healthcare Professional	PMM	-	US GMM and/or MRI GMM, EDM, GMKT, LA, MA	-
3В	Contract terms review	Final Contract Doc.	PMM	LA	GMKT, US GMM and/or MRI GMM	-
4B	Contract Signature	Contract Signed	US GMM and/or MRI GMM	PMM	-	LA, GMKT



Step	Activity	Document in- out / Transaction	R	A	С	I
5B	PMM executes contract terms till the final contract expiration		PMM	-	GMKT, LMKT, LAS	US GMM and/or MRI GMM, LCM, RBD, FA



# 6.3. Collaboration (and Loan for Use) Agreement: Marketing & Healthcare Organization/Marketing & Healthcare Professional - Local entities Activities and Actions

This section provides the detailed process operations relevant to the KOLs activities represented by a **Healthcare Organization** or **Healthcare Professional** in cooperation with Local entities worldwide both in human and veterinary application fields in US and dedicated MRI. The present process applies both to new products and installed base.

The activities are focused on the collection of marketing material (e.g. clinical images/clips, white papers, eBooks, posters, APPs/libraries, publications/articles/videos, social media posts, and similar), the execution of educational plans and customer's visits.

Step	Activity	Document in-out / Transaction	R	А	С	I
1	LMKT identifies the KOL (Healthcare Organization or Healthcare Professional) and relevant activities according to the local marketing needs for both human and veterinary topics in US and MRI	-	LMKT	LCM, RBD	LAS	GMKT, US GMM and/or MRI GMM, FV, FA
2	LMKT prepares the KOL contract according to the standard agreements ( <b>Healthcare</b> <b>Organization</b> or <b>Healthcare Professional</b> ) for both human and veterinary topics in US and MRI	MKT Healthcare Organization / MKT Healthcare Professional	LMKT	LCM, RBD	LAS, FV, LCM, RBD, LA	GMKT, US GMM and/or MRI GMM, FA
3	Contract terms review	Final Contract Doc.	LMKT	LA	PMM, US GMM and/or MRI GMM	-
4	Contract Signature	Contract Signed	LCM, RBD	LMKT	-	LA, PMM, US GMM and/or MRI GMM
5	LMKT executes contract terms till the final contract expiration		LMKT	LCM, RBD	LAS, FV	GMKT, US GMM and/or MRI GMM, FA



The documents related to the execution of the contract and the activity conducted are stored at the local Head of Function secretary.



All rights are strictly reserved.

# **6.4.** KOL Service Agreement - GMKT/LMKT Activities and Actions

This section provides the detailed process operations relevant to KOLs management for their participation to worldwide exhibition booth/workshops/events/meetings in order to support the Esaote sales and marketing teams (ref. Section A for GMKT, and Section B for LMKT) for both human and veterinary topics in US and MRI. The present process applies both to new products and installed base.

Step	Activity	Document in-out / Transaction	R	A	С	I
1A	GMKT identifies KOL within the worldwide KOLs matrix and activities to be performed at exhibition booth/worldwide workshops/events/meetings for both human and veterinary topics in US and MRI	-	GMKT	-	US GMM and/or MRI GMM, PMM, AS/EDM, LMKT, FV, LCM, RBD	-
1B	LMKT identifies KOL within the local KOLs matrix and activities to be performed at exhibition booth/local workshops/local events/meetings for both human and veterinary topics in US and MRI	1	LMKT	LCM, RBD	LAS, FV, GMKT, US GMM and/or MRI GMM	-
2A	GMKT prepares the KOL contract according to the standard agreement (KOL Services Agreement) for both human and veterinary topics in US and MRI	KOL Services Agreement	GMKT	1	PMM, EDM, AS, US GMM and/or MRI GMM, LA	LCM, RBD, FA
2B	LMKT prepares the KOL contract according to the standard agreement (KOL Services Agreement) for both human and veterinary topics in US and MRI	KOL Services Agreement	LMKT	-	LAS, FV, LCM, RBD, LA	GMKT, US GMM and/or MRI GMM, FA



Step	Activity	Document in-out / Transaction	R	Α	С	ı
3A	GMKT executes contract terms till the final contract expiration		GMKT	-	PMM, EDM, AS	LCM, RBD, LMKT, US GMM and/or MRI GMM, FA
3B	LMKT executes contract terms till the final contract expiration		LMKT	LCM, RBD	LAS, FV	GMKT, US GMM and/or MRI GMM, FA



# 6.5. Collaboration (and Loan for Use) Agreement: MA& Healthcare Professional - Healthcare Professional for PMS activities

Post-market Surveillance and Clinical Evaluation processes apply to US and MRI devices intended for human use only.

This section provides the detailed process operations performed by MA related to Post Market Clinical Follow Up (PMCF) activities.

Those activities are needed when:

- 1. New clinical data are necessary to confirm and sustain the demonstration of the conformity with the Essential Requirements for performance and/or safety of the device already on the market as part of the PMS process AND/OR
- 2. New features introduced in a product pose some doubts on mid-long terms maintenance of the essential requirement for safety and/or performance of the device. In such a case Post Market Surveillance Clinical Follow Up Studies (PMSCF) can be made to follow up and monitor the behavior of the device in the time

PMCF Activities can be conducted either by collecting feedbacks and user experience by HCPs from clinical sites and or supporting an Investigator-Initiated Trial (IIT).

The present process applies both to new products and/or installed base.



Step	Activity	Document in-out / Transaction	R	A	С	I
1	POST-Market Clinical Follow Up Activities has to be conducted by collecting feedbacks and user experience from clinical sites and or supporting an Investigator-Initiated Trial (IIT) for both US and MRI	PMCFS Plan	MAL, GMKT, LMKT	MAL	-	PMM, PM
2	Identification of the clinical site(s) suitable to collecting feedbacks and user experience from clinical sites and/or supporting an Investigator-Initiated Trial (IIT)	-	MAL	MAL	PM, PMM	-
വ	MA prepares the KOL contract according to the standard agreement (KOL Services Agreement) for human and topics in US and MRI and collects any eventual annex document to the contract	Collaboration (and Loan for Use) Agreement: MA & Healthcare Professional for PMCF Activities	MAL	-	-	LA
4	Contract terms review	Final Contact Doc.	MAL	LA	-	-
5	Contract Signature	Contract Signed	CQO	MA	-	LA, PMM, PM
6	MA executes contract terms till the final contract expiration		MA	-	US GMM and/or MRI GMM, US RD and/or MRI RD	LE



# **6.6.** Pre-Market Clinical Trials Agreement: Medical Affairs Objectives - MA Activities and Actions

This section provides the detailed process operations relevant to the Medical Affairs activity the, due to the innovation introduced in the product, for which the demonstration of the conformity with the Essential Requirements of performance and safety cannot be done by the appraisal and the critical review of the pertinent data currently available from the scientific literature.

In this case pre-market clinical investigation are needed.

This activity will be conducted as an Esaote-Initiated Trial (EIT) and they have to be managed according to the provision set by UNI EN ISO 14155:2012 "Clinical investigation of medical device on human subjects – Good clinical practice" and local legal binding laws in force in the country where the selected clinical sites are located.

During EIT planning phase, MA will identify the Clinical site(s) suitable for the conduction of the study, LA will support MA in assessing the binding Laws in force in the state/states in which the Clinical site(s) is/are located.

During the EIT planning phase, the insolvent of CRO will be assessed and defined and in case of need the third party CRO will be identified and contractual term defined.

During EIT planning phase, LA will assist MA in the definition of the contractual framework with the clinical sites and CROs ensuring the company to enforce the compliance to the local binding.

The present process applies both to new products and installed base.

Step	Activity	Document in- out / Transaction	R	А	С	I
1	PRE-Market Clinical Study has to be conducted by means an Esaote-Initiated Trial (EIT), according to the provision set by UNI EN ISO 14155 and local binding Laws		MA	MAL	PM, PMM	-
2	Identification of the clinical site(s) suitable to conduct the Esaote-Initiated Trial (EIT),		MA	MAL	PM, PMM	-
3	Identification of the CRO(s) suitable to perform one or more of the Esaote's clinical investigation-related duties arising from the conduction the Esaote-Initiated Trial (EIT)		MA	MAL	-	-
4	LA assesses the binding Laws framework in force in the state/states hosting the clinical study and CRO	Contractual terms definition	CLGCO	LA	MA	PM, PMM
5	Contract terms review: LA assists MA in all the formal acts	Final Contract Doc.	MAL	LA	PM, PMM	-



Step	Activity	Document in- out / Transaction	R	А	С	I
	enforcing compliance to local binding laws					
6	Contract Signature	Contract Signed	MAL	CQO	-	LA, PMM, PM, US GMM and/or MRI GMM
7	Esaote-Initiated Trial (EIT) conduction and execution according to the provision set by UNI EN ISO 14155 and local binding Laws	Documentation as per ISO 14155:2011 Annex 3 (Table E.1 Essential Documents prior to clinical investigation; Table E.2 Essential Document during Clinical investigation; Table E.3 Essential document after clinical investigation)	MA	MAL	PM, PMM	-
8	MA executes contract terms till the final contract expiration		MA	MAL	US GMM and/or MRI GMM, RD	LE



# 6.7. Collaboration (and Loan for Use) Agreement: RD & Healthcare Organization - RD Activities and Actions

This section provides the detailed process operations performed by RD Team relevant to the product feature/technology development in cooperation with KOLs represented by a Healthcare Organization. The present process applies both to new products and installed base.

This section is focused on the product development to be conducted on-site by RD in order to receive the KOL's feedbacks upon the overall product performances (features and technology). This activity might include the free loan of use option relevant to products/parts under external evaluation, refer to Collaboration (and Loan for Use) Agreement with HCOfor Research & Development".

The RD documentation is intended to be created following to the KOL activities.

Step	Activity	Document in- out / Transaction	R	А	С	I
1	RD identifies the KOL (Healthcare Organization) and relevant activities according to the product Company strategy for both human and veterinary topics in US and MRI	1	SYSM (MRI)/SY S_ADI (US)	-	PMM,PM, LMKT, FV, LCM, RBD,	US GMM and/or MRI GMM
2	RD prepares the KOL contract according to the standard agreement for both human and veterinary topics in US and MRI	RD & Healthcare Organization	SYSM (MRI)/SY S_ADI (US), PL	SYSM (MRI)/ SYS_A DI (US)	LA	PMM, PM, PL, LMKT, FV, LCM, RBD, US GMM and/or MRI GMM
3	Contract terms review	Final Contract Doc.	SYSM (MRI)/SY S_ADI (US), PL	LA	PMM, PM, PL	-
4	Contract Signature	Contract Signed	СТО	-	-	LA, PMM, PM, PL, LMKT, FV, LCM, RBD, US GMM and/or MRI GMM
5	RD executes contract terms till the final contract expiration		SYSM (MRI)/SY S_ADI (US), PL	SYSM (MRI)/ SYS_A DI (US)	PM, PMM, PL	US GMM and/or MRI GMM, LMKT, LCM, RBD, FV, FA



# 6.8. Collaboration (and Loan for Use) Agreement: RD & Healthcare Professional - RD Activities and Actions

This section provides the detailed process operations performed by RD Team relevant to the product feature/technology development in cooperation with KOLs represented by a **Healthcare Professional**. The present process applies both to new products and installed base.

This section is focused on the product development to be conducted on-site by RD in order to receive the KOL's feedbacks upon the overall product performances (features and technology). This activity might include the free loan of use option relevant to products/parts under product development activity, refer to "Collaboration (and Loan for Use) Agreement: RD Objectives".

The RD documentation is intended to be created following to the KOL activities.

Step	Activity	Document in-out / Transaction	R	А	С	I
1	RD identifies the KOL (Healthcare Professional) and relevant activities according to the product Company strategy for both human and veterinary topics in US and MRI		SYSM (MRI)/SYS_ADI (US)	-	PMM,PM, LMKT, FV, LCM, RBD,	US GMM and/or MRI GMM
2	RD prepares the KOL contract according to the standard agreement for both human and veterinary topics in US and MRI	RD & Healthcare Professional	SYSM (MRI)/SYS_ADI (US), PL	SYSM (MRI)/SYS_ADI (US)	LA	PMM, PM, PL, LMKT, FV, LCM, RBD, , US GMM and/or MRI GMM
3	Contract terms review	Final Contract Doc.	SYSM (MRI)/SYS_ADI (US), PL	LA	PMM, PM, PL	-



Step	Activity	Document in-out / Transaction	R	А	С	I
4	Contract Signature	Contract Signed	СТО	-	-	LA, PMM, PM, PL, LMKT, FV, LCM, RBD, US GMM and/or MRI GMM
5	RD executes contract terms till the final contract expiration		SYSM (MRI)/SYS_ADI (US), PL	SYSM (MRI)/SYS_ADI (US)	PM, PMM, PL	US GMM and/or MRI GMM, LMKT, LCM, RBD, FV,



# 7. KOL Fee and Travel Policy

This section provides the detailed process operations relevant to the KOL fee and Travel Policy for the activities performed by the KOLs (**Healthcare Professional**) at exhibition booth/workshops/events/meetings (ref. Section A for Local Entity activities, and Section B for GMKT activities). The KOLs activity fee conditions are included in the KOL "Collaboration (and Loan of Use) Agreement: Marketing/RD & Healthcare Professional", see Par 6.2. and Par 6.8. The travel fee policy is included in the "KOL Services Agreement", see Par 6.4.

Step	Activity	Document in-out / Transaction	R	А	С	I
1A	LCM defines the KOL travel conditions according to the business activity following the Company travel policy strategy for both human and veterinary topics in US and MRI	-	LCM	-	RBD, LMKT, FV, GMKT, US GMM and/or MRI GMM	-
1B	US GMM and/or MRI GMM defines the travel conditions according to the business activity following the Company travel policy strategy for both human and veterinary topics in US and MRI	-	US GMM and/or MRI GMM	-	GMKT, LMKT, FV, LCM, RBD	-
2A	RBD approves the KOL daily activity fee: - 500 to 1000 Euros depending on business activity - specific cases above 1000 Euros need to be discussed/approved	-	RBD	-	LCM, LMKT	-
	<ul> <li>Travel conditions:</li> <li>Economy Class below 6 hours flight</li> <li>Business Class above 6 hours flight</li> <li>specific different cases need to be discussed/approved</li> </ul>					



Step	Activity	Document in-out / Transaction	R	Α	С	I
2B	US GMM and/or MRI GMM approves the KOL daily activity fee: - 500 to 1000 Euros depending on business activity - specific cases above 1000 Euros need to be discussed/approved	-	US GMM and/or MRI GMM	-	GMKT, LMKT, LCM, RBD	-
	<ul> <li>Travel conditions:</li> <li>Economy Class below 6 hours flight</li> <li>Business Class above 6 hours flight</li> <li>specific different cases need to be discussed/approved</li> </ul>					

# 8. Contracts

All the agreements concerning the interactions regulated under these Guidelines must comply with the general requirements (as applicable) specified in Paragraphs 5.1 and 5.2 and must be in writing.

The process requirements specified in Section 6 and with the fees and travel policy requirements specified in Section 7 must always be complied with.

Attached to these Guidelines are the following standard agreements:

- Collaboration (and Loan for Use) Agreement with HCO Marketing activities;
- 2. Collaboration (and Loan for Use) Agreement with HCO Research & Development activities;
- 3. Collaboration (and Loan for Use) Agreement with HCP Marketing activities;
- 4. Collaboration (and Loan for Use) Agreement with HCP Research & Development activities;
- 5. Collaboration (and Loan for Use) Agreement for Medical Affairs Objectives;
- 6. Service Agreement with HCP.

The function initiating the process is responsible for defining the exact and appropriate scope of work of the agreement.

The responsibility of ensuring localization of this standard under local applicable laws stays within the relevant company in Esaote Group.

# 9. Revision info

All rights are strictly reserved.

Guidelines approved and published on February 4<sup>th</sup>, 2019. Version 02 approved and published on February 21<sup>st</sup>, 2020



# COLLABORATION (AND LOAN FOR USE) AGREEMENT WITH HEALTHCARE ORGANIZATION (HCO)

- This standard is attached to Esaote Group Key Opinion Leaders Guidelines;
- This standard is ruled under Italian Law;
- The responsibility of ensuring localization of this standard under local applicable laws stays within the relevant company in Esaote Group;
- The same standard applies for:
  - Marketing;
- The function initiating the process is responsible for defining the exact and appropriate scope of work of the Agreement.

This page is merely explanatory and must be removed from the agreement draft.

### COLLABORATION (AND LOAN FOR USE) AGREEMENT

#### BETWEEN

ESAOTE S.p.A., with headquarters in Via Enrico Melen, 77 - 16152, Genoa, Italy, Taxpayer Identification and VAT Code No. 05131180969, hereinafter simply referred to as **ESAOTE**, represented by its Representative [•], endowed with the necessary powers,

#### AND

[•], hereinafter simply referred to as **Healthcare Organization** ("HCO")

#### WHEREAS

- The HCO has several years of international experience in the field of diagnosis and therapy at high and medium intensity of care and propose to ESAOTE an agreement to loan for use ESAOTE equipment for specific scientific purposes for improving health.
- ESAOTE has for years been engaged in the development of innovative ultrasound technology with high spatial resolution, MRIs, and diagnosis support clinical software, focusing on specific pathologies.
- ESAOTE is interested in collaborating with the HCO, making available its knowledge
  and equipment, on a temporary basis and under the conditions herein laid out, to the
  collaboration activities herein agreed.
- 4. ESAOTE holds, and shall continue to hold for the entire duration of this Agreement, all the authorizations and licenses necessary to own full rights over the trademark (word and figurative) reproduced in Attachment 3 (hereinafter the "Trademark"), and to grant rights under this Agreement. ESAOTE wishes to promote its products, business, and image, within the territory, in compliance with its ethical principles;
- Also pursuant to Anac resolution n° 831/2016, the Parties specifically declare and acknowledge that no compensation shall be granted to ESAOTE pursuant to this Agreement and ESAOTE will loan the use of the equipment free of charge.

### THE PARTIES THEREFORE AGREE AND COVENANT AS FOLLOWS

### Article 1 - Recitals

The Recitals are an integral and substantive part to this Agreement.

### Article 2 - Object

By this Agreement the Parties agree to carry out collaborative activities in the following areas, as further detailed below ("Activities"):

- 1. Teaching/Training
- 2. Collection of environmental videos and pictures
- 3. Collection of clinical images and clips
- 4. Development of White Papers, Promotional Material, Interviews
- 5. Test (post CE marking) connected with the IQ Software release

#### Article 3 - Performance of the Activities

The Activities shall be carried out as detailed in Attachment 2 herein.

The HCO represents and warrants to have completed all the necessary procedures and to have obtained all the necessary authorizations to sign and perform this Agreement in compliance with the applicable laws and regulations.

### **Article 4 - Activities of the Institution**

The HCO agrees to:

- Indicate, in every type of documentation produced, that the activities have been carried out with ESAOTE equipment.
- Maintain appropriate records in relation to the provision of the Equipment by ESAOTE, including proof of receipt for any Equipment delivered by ESAOTE and proof of delivery of any Equipment returned to ESAOTE.
- 3. Provide the following reports within the timeframes indicated below:

Frequency	Report
6 months	- Semiannual report, calculated starting
	on the date of validity of this
	Agreement.
	- Final Report on the performance of the
	Activities.

4. Enable the members of staff of ESAOTE, as previously communicated by ESAOTE, to carry out jointly agreed visits for the purpose of assisting in the Activities and reaching the objectives detailed under Attachment 2 hereto.

### Article 5 - Loan for Use

For the purpose of assisting in the Activities, ESAOTE makes available to the HCO, under a free-of-charge Loan for Use, one piece of equipment, with CE marking, in compliance with the European directive on medical devices, and described in Attachment 1 herein ("Equipment"), and agrees to provide introductory training for the purpose of using the Equipment to the doctors who shall make use thereof, with the expected duration of 1 (one) week. The Equipment shall be placed within the facilities of the HCO and shall be used with care and diligence. The HCO shall abstain from any use of the Equipment other than those expressly granted under this Agreement and/or necessary to perform the Activities.

The HCO shall bear any costs connected with the use of the Equipment. For the entire duration of this Agreement ESAOTE shall bear all the costs relative to an insurance policy covering against fire and theft, and to the ordinary and extraordinary maintenance of the Equipment. Consumables are expressly excluded.

The HCO shall be held liable for any loss and/or damage to the Equipment caused by the negligence of the users, for any reason whatsoever.

The HCO expressly indemnifies and holds ESAOTE harmless form any liability for damages to persons of things deriving from the use of the Equipment, unless said damages are caused by flaws and/or design and/or manufacturing defects. Pursuant to and by effect of Article 1806 of the Civil Code, any damage or loss of the Equipment will be charged to the HCO, also in the event that such damage or loss is due to unforeseeable circumstances or is not attributable to the HCO. To this effect, the Parties estimate the total value of the Equipment in [•]. Upon termination of this Agreement, ESAOTE shall remove the Equipment at its sole care and expense.

Article 6 - Confidentiality

- The HCO guarantees that the staff appointed to carrying out the Activities shall
  maintain, towards any non-authorized person, full confidentiality as regards to any
  information, knowledge on the performance and the status of the Equipment, as well
  as to any confidential document they may become aware of within the scope of this
  Agreement or any future agreement and/or protocol.
- 2. The HCO agrees to treat as confidential and not to disclose, either directly or indirectly, any information concerning ESAOTE and the products designed by the latter, of which they may gain knowledge during the performance of the Activities. Specifically, the HCO acknowledges that such information shall be deemed property of ESAOTE, and agrees:

Commentato [OF1]: PLEASE SPECIFY

- to keep said information as confidential, and disclose it exclusively to members of staff of the HCO limited to what is strictly necessary for the purpose of performing the Activities, demanding the strictest confidentiality.
- not to copy, disassemble, or in any way interfere with the hardware and the software of ESAOTE S.p.A.'s Equipment.
- if required by ESAOTE, promptly return every piece of written information and any copy thereof.
- This confidentiality agreement does not apply to any information already in the public domain or which was available to the HCO at a time prior to the signing of this Agreement.
- 4. This confidentiality agreement is binding for the duration of this Agreement and for a period of five (5) years after the termination thereof.

## Article 7 - Obligation of the HCO and use of the trademark

- ESAOTE grants to the HCO the right to use the Trademark, exclusively in the measure in which the use of the Trademark is necessary to the HCO to carry out the Activities, for the duration and under the condition laid out in this Agreement.
- 2. The HCO shall be entitled to no right to use the Trademark other than those expressly granted herein. In particular, the HCO shall not have the right to transfer and/or grant in any way to any third party the right to use the Trademark, and undertakes to abstain from any conduct and/or from promoting any initiative connected to the Trademark, and, in any case, to the image of ESAOTE, other than those expressly provided under this Agreement, or which may damage in any way the Trademark or the image of ESAOTE.
- 3. The Parties acknowledge and agree that, at any time during the duration of this Agreement, ESAOTE may request the HCO, via written communication, to cease to use the Trademark, or to use a modified or different mark (the "Modified Trademark"), which shall be communicated by the HCO in the same manner.
  - The HCO shall cease to use the Trademark upon receipt of ESAOTE's request, and shall refrain from using the Trademark until receipt of a written communication from ESAOTE requesting otherwise. Should ESAOTE request the HCO to use the Modified Trademark, the HCO shall use the Modified Trademark as soon as reasonably possible, and, in any case, no later than a month after receipt of the notification from ESAOTE. In this case, the costs and expenses required to promptly use the Modified Trademark shall be borne by ESAOTE, by reimbursing the HCO promptly upon

receipt of a suitable written evidence of said costs and expenses and a relative invoice.

### Article 8 - Persons in Charge of the Collaboration

Person in charge of the Activities for ESAOTE: the project head appointed by ESAOTE to interact with the HCO shall be [•], who shall liaise with the HCO for anything relating to the performance of the collaboration and of this Agreement.

Person in charge of the activities for the HCO: the scientific project head of the collaboration, and person in charge appointed by the HCO to interact with ESAOTE shall be, [•], who shall liaise with ESAOTE for anything relating to this Agreement, and more specifically, within the scope of the Agreement, sign any formal instrument (report, document, or correspondence).

ESAOTE and the HCO agree to promptly notify in writing the other Party of any variation to the above persons appointed.

The persons appointed for the purpose of the collaboration shall be in charge of organizing one or more training and briefing meetings with ESAOTE's staff on the activities carried out and the results achieved.

### Article 9 - Duration

This Agreement shall be valid from [●] until [●]. Tacit renewal is expressly excluded.

### Article 10 - Compliance with law and policies

The HCO shall perform the Agreement and shall conduct all the Activities in compliance with applicable laws, regulations and professional codes of conduct (including the Assobiomedica code of conduct and COCIR principles).

The management of any relationship and activity involving healthcare professionals who operate for the HCO is under the exclusive responsability of the HCO, including any compensation due or paid to such professionals.

The HCO acknowledges and confirm that Loan for Use of the Equipment does not improperly reward, induce and/or encourage the HCO and/or any HCO's directors, officer or employee to purchase, lease, recommend, use, supply or procure any ESAOTE's product or service.

In any case the HCO shall conduct the Activities in a manner to avoid and, in case, to promptly disclose and resolve any Conflict of Interest which may arise in the interactions between the Parties and/or their directors and officers. For the purpose of this clause "Conflict of Interest" means any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision. The HCO acknowledges that ESAOTE adopted: (i) a Code of Conduct, (ii) an Organization,

Management and Control Model in compliance with Legislative Decree No. 231 of 2001, and (iii) a policy regulating the interactions with Healthcare Organizations and Healthcare Professionals whose principles are here attached under "4" (the "Policy"). The provisions of the Code of Conduct and the Organization, Management, and Control Model can be found on the website <a href="www.esaote.com">www.esaote.com</a>, and constitute an integral and substantive part to this Agreement.

In the performance of the Activities herein set out the HCO agrees to adhere to and comply with ESAOTE's Code of Conduct, the Organization, Management, and Control Model and the Policy, insofar as they are applicable to the HCO, and thus, by signing this Agreement, the HCO also agrees to comply with the provisions therein contained.

In case of violation by the HCO of any obligation set forth under this clause, ESAOTE shall be entitled, pursuant to Article 1456 of the Italian Civil Code, to terminate this Agreement for all purposes of law, and to bring action against the HCO to claim compensation of the relative damages.

# Article 11 - Hygiene and Safety in the Workplace - Mutual Disclosure on Specific Risks and Management of Risks from Interferences

- ESAOTE guarantees full compliance with the obligations provided under Legislative Decree 81/08, as amended, for the purpose of protection of the health and safety of its workers in the work place.
  - Should ESAOTE's staff, in line with the times and as provided in this Agreement, occasionally visit in work environments under the legal control of the HCO, including in areas featuring risks other than those specifically assessed by ESAOTE, the latter undertakes to provide to the HCO all the necessary and sufficient information on the risks connected with ESAOTE's activities, for the purpose of enabling the HCO to analyze possible interferences between works. ESAOTE agrees to provide its full collaboration necessary to such end.
- 2. In the performance of the activities herein agreed, the HCO agrees to keep ESAOTE informed of the risks present in the areas where ESAOTE's members of staff may operate, promoting a full cooperation and coordination activity, and the drafting of a Single Document for the Assessment of Interference Risks (Documento Unico di Valutazione dei Rischi da Interferenza, or

*DUVRI*) pursuant to Article 26 of Legislative Decree 81/08, as amended, which is to be deemed an integral and substantive part to this Agreement.

# Article 12 - Personal Data Processing

By executing this Agreement the HCO, acknowledges to be Data Owner of the data collected, registered, organized and saved in the memory of the Equipment.

In the event that ESAOTE, during the performance of this Agreement carries out any activity relating to the processing of data pursuant to art. 4, par. 2) of the European Regulation 679/2016 - GDPR, the HCO undertakes to promptly appoint ESAOTE as External Processor pursuant to art. 28 of the above mentioned European Regulation, under the following conditions:

# Data processor shall:

- a) process Personal Data in accordance with and for the specific purposes of the performance of Technical Service Activities and pursuant to the Information Notice attached to the General Terms and Conditions
- b) maintain the highest level of confidentiality about the Personal Data;
- ensure that people authorized to the processing of Personal Data under the authority of the Data Processor is bounded to the duty of confidentiality;
- train people authorized to process Personal Data under the authority of the Data Processor and provide them with adequate instructions relating to data processing activities, monitoring the compliance;
- e) ensure that adequate technical and organizational measures are implemented to ensure a level of security appropriate to the risk, in accordance with Art. 32 of GDPR;
- f) assist the Data Controller, to the extent applicable, in the execution of the Data Protection Impact Assessment and prior consultation, in accordance with Art. 35 and 36 of the Regulation;
- g) appoint System Administrators and monitor their activity in compliance with the Provision issued by the Data Protection Authority on November 27, 2008 (and subsequent amendments and additions);
- h) promptly both communicate to the Data Controller criticalities and flaws concerning data protection and indicate whether any instructions received by the Data Controller, in its opinion, violates the GDPR or other provisions relating to data protection;
- i) inform the Data Controller about investigations carried out by the Data Protection Authority or any other Authority that involve Personal Data;
- j) notify the Data Controller any Personal Data breach likely to result in a risk to the rights and freedoms of the data subjects, according to the manner and providing all the information pursuant to art. 33 of the GDPR and supporting the Data Controller for the consequent communications to the data subjects referred to in art. 34 of the GDPR;
- k) keep a written record of the processing activities carried out on behalf of the Data Controller pursuant to art. 30 of the Regulation provide to the Data Controller a report showing the status of the activities carried and the measures put in place to comply with GDPR pursuant to art. 30 of the GDPR;
- l) when the Data Processor needs to transfer Personal Data to a third country or an international organization in compliance with Union or Member State law, it informs the

- Data Controller of this legal requirement before processing, unless that law prohibits such information on important grounds of public interest;
- m) for the purposes of processing Personal Data for the purposes under letter a) above, in the case where the Data processor intends to make use of Sub-Processors or in the case where any information provided to the Data Controller is to be updated or amended, the Data Processor shall previously inform the Data Controller including the identity, contact details and the relevant activities carried out by the Sub-processors. In case the Data Controller does not make opposition within 5 days from the notification by the data processor, the use of the sub-contractor and appointment of sub-processor shall be authorized.
  - In case of the appointment of Sub-Processor, the Data Processor shall impose on the same the obligations set out in these Conditions. If, furthermore, the Sub-Processor fails to comply with its data protection obligations, the Data Processor retains the entire responsibility for the fulfillment of the obligations of the other party towards the Data Controller.
- delete or return all the personal data after the end of the provision of services relating to the processing and delete existing copies, unless Union or Member State law requires storage of the personal data;
- o) make available to the Data Controller all the information necessary to demonstrate compliance with the obligations referred to in this appointment letter and allow and contribute to the review activities, including inspections, carried out by the data controller or another person appointed by them.

ESAOTE will process the HCO personal data as per the Information Notice here attached under "5".

In addition to the above, at the termination of this Agreement, the HCO undertakes to return the Equipment without any data ownership of which is of the HCO.

It remains understood that ESAOTE will have the right to receive data anonymized according to ESAOTE Procedure here attached under "6" regarding data subjects collected and/or anyhow processed ny means of the System.

ESAOTE will be therefore authorized to freely use anonymized data received and/or obtained as described above in order to improve ESAOTE products and/or services and/or to develop new products and/or services with no obligation to grant anything to the HCO for any reason whatsoever.

To this effect, the HCO declares and acknowledges that ESAOTE anonymization process is legitimate as well as the subsequent use of anonymized data for the abovementioned purposes.

The HCO also declares and guarantees to have all necessary authorizations and consents for for processing personal data to the effect of this Contract.

The HCO undertakes to release ESAOTE from any consequence, loss of action, even carried out by third parties, deriving from the violation by the HCO of the declarations and warranties here described.

# Article 13 - Governing Law and Jurisdiction

This Agreement is governed under the laws of the Republic of Italy.

Any dispute arising out of or in connection to the interpretation or performance of this Agreement shall be subject to the exclusive jurisdiction of the Court of Genoa, Italy.

Read, confirmed, and signed		
For the HCO		
For ESAOTE		

Description of the equipment object to this Agreement as per point 5.

Code	Description
[•]	[•]
	Add Probes or Other

# Description of the Activities

# Teaching/Training:

Description of the Activity: <fill in according to the activity>
Course of Action: <fill in according to the activity>
Expected Results: <fill in according to the activity>

# Collection of Environmental Video and Pictures

Course of Action: <fill in according to the activity> Expected Results: <fill in according to the activity>

# Collection of Clinical Images and Clips:

Expected Results: <fill in according to the activity>
The HCO agrees to provide to ESAOTE the data and images collected, in anonymous form and in any case in the respect of the patients' privacy.

# Development of Promotional Material, including White Papers and Interviews:

Expected Results: <fill in according to the activity>

# Tests (post CE marking) connected with the IQ Software release:

Description of the Activity: <fill in according to the activity>
Course of Action: <fill in according to the activity>
Expected Results: <fill in according to the activity>

# COMPANY TRADEMARK AND TRADEMARK USE REGULATION

#### TRADEMARK



# RULES FOR THE OCCASIONAL AND TEMPORARY USE OF THE ESAOTE TRADEMARK

# SECTION 1. - LEGAL OWNERSHIP AND DESIGNATION OF THE TRADEMARK

Esaote is the legal owner of the trademark described in section No. 2 of these rules. Individuals who are granted authorization to make occasional and temporary use of the Trademark expressly recognize that Esaote is the sole legal owner of the Trademark; moreover, they recognize the value and goodwill associated with the trademarks and acknowledge that value and goodwill belong exclusively to Esaote. They further recognize that the right to use the Trademark must be exercised in strict obedience to the conditions and Terms of these rules, and that they will not at any time or in any way acquire any further rights to the trademark, under its use in the forms authorized by Esaote.

# SECTION 2. - DESCRIPTION OF THE TRADEMARK

The trademark



corresponds to the characteristics described in document No. MAK000115 Ver. 01 "Corporate Identity - The new guidelines for the use of the Esaote Trademark and its applications".

# SECTION 3. - PURPOSES AND AIMS OF THE TRADEMARK

By means of the Trademark, Esaote intends to pursue the following goals:

- to promote the corporate image;
- to identify technologies, activities, and services generated by the Company;
- to enhance less invasive, more accessible methods of diagnostic imaging, offering, at the same time, higher efficiency standards, such as those developed by Esaote;
- to spread the values of creativity, innovation, and excellence in research and development that are particular to the Company's story.

For these key reasons, the trademark must be protected and safeguarded.

#### SECTION 4. OWNERSHIP OF THE TRADEMARK

The Trademark is owned exclusively by Esaote SpA.

Only Esaote has the right to authorize the use of the Trademark by third parties who so request it, specifying the terms, methods and limits of that use.

#### SECTION 5. USE OF THE TRADEMARK

Individuals who are granted authorization to make temporary and occasional use of the Trademark undertake:

- to not use the Trademark in any way, not even through a third person, if it is not included in the ways provided by these Rules, by the manual "Guidelines for the use of the Esaote Trademark" or, anyhow, by the forms specifically established at the moment of authorization;
- to not use in any way, even through a third person, distinguishing images, other images, words, or names that are similar to and/or may be confused with the Trademark;
- to not register trademarks or domain names in their own name that incorporate the words, letters, writing, images or colors that characterize the Trademark, nor any trademark that could be confused with that of Esaote or that is based on it or that could be considered derived from it in any way;
- to not make any sort of variation, addition, or graphic, chromatic or literal modification to the trademark, that is, to not use the trademark in connection, combination, or together with other trademarks, names, words, images, symbols, or colors without prior written approval from Esaote;
- to not depict, display, or promote together with the depiction of the Trademark, trademarks referring to or products made by Esaote's competitors;
- to not sub-grant, transfer, or authorize use of the Trademark to third parties, as that use must only be made directly by the individuals authorized by Esaote;
- to not grant to third parties in sub-license or to any other titles the right or power to use the Trademark, even only partially, as granted by Esaote.

Esaote reserves the right to demand suspension of all forms of the Trademark's use at any time, when that use is not made in compliance with the conditions here defined.

Consequently, the user cannot make partial use of the Trademark nor modify it in any way, but must use it in its entirety, and in the shapes, dimensions, graphic depiction, and colors as provided by the manual "Guidelines for the use of the Esaote Trademark", or in any case, in the forms specifically established at the moment of authorization. The Guidelines' duration is unlimited.

# SECTION 6. DURATION OF THE AUTHORIZATION

The duration of the right to use the Trademark will be determined at the time of authorization, with expiration of all rights of use occuring for that defined period without the necessity of any formal correspondence, except in cases of suspension, revocation, forfeiture, or cancellation, in accordance with the methods described in sections 9, 10, and 11 of these rules.

# SECTION 7. TRADEMARK PROTECTION

Use of the trademark for activities in contrast with Esaote's constitutional aims is strictly prohibited.

The user recognizes the trademark's prestige and, consequently, undertakes to use the trademark with the utmost care and diligence. As such, all activities carried out by the user while using the Esaote trademark must be performed in such a way so as not to damage Esaote's image or in any way harm the trademark's reputation. In particular, the user agrees not to use the Trademark in a way that is deceptive toward the public.

The user recognizes that the trademark is the exclusive property of Esaote and agrees to immediately inform the same of any third party action or event that may constitute a real or suspected violation of the rights of Trademark ownership, reporting every objection, complaint, or warning related to the use of the Trademark, as well as any falsification that has come to his/her attention.

The user and Esaote will, therefore, lend each other reciprocal collaboration in every effort meant to protect and defend the trademark, subject to Esaote's full autonomy and discretion in the adoption of measures deemed opportune for the purposes above indicated.

Esaote may carry out inspections, directly or via third parties, to ensure the correct use of the trademark

In accordance with that which is provided by trademark protection law, Esaote has the right to initiate legal proceedings against all those who use the trademark without prior authorization.

#### SECTION 8. NON-AUTHORIZED USE OF THE TRADEMARK

In the case of non-authorized use of the Trademark or use of the Trademark that diverges from the regulations imposed at the time of authorization, Esaote will order immediate cessation of the use, as well as the destruction of all related materials or the interruption of all activities deemed damaging to Esaote's rights, operating in the appropriate central offices for the protection of its rights.

Use of the Trademark by any individual who is not authorized or in divergence with respect to the terms of authorization will be prosecuted by Esaote in accordance with the measures provided by national and international laws for the protection of intellectual property.

# **SECTION 9. CANCELLATION AND FORFEITURE**

With all other powers of cancellation according to the provisions of the law still holding, noncompliant use of the trademark with respect to the terms and methods established by these Rules, by the Guidelines for the Use of the Esaote Trademark, and by the specific regulations potentially dictated by Esaote at the time of authorization will entail Esaote's right to cancel the

contract pursuant to and in accordance with Art. 1456 of the Italian Civil Code, with the associated automatic rescindment of the authorization.

If Esaote voluntarily ends use of or modifies the Trademark, existing authorizations for the use of the Trademark expire automatically without any expenses charged to Esaote.

In all cases of suspension of the effects of authorization for the use of the Trademark, including expiration, cancellation, and forfeiture, the user is duty bound to immediately cease any activity that involves the use and depiction of the Trademark, and in any case, to cease any distribution of materials in which the Trademark is depicted (such as catalogues, leaflets, labels, websites, or any other communicative material).

# SECTION 10. REVOCABILITY OF THE AUTHORIZATION

Authorization for the use of the trademark may be unilaterally revoked by Esaote at any time. Anyhow, the contract will be understood as cancelled by operation of law in the case of:

- a) bankruptcy or subjection to other insolvency procedures on the part of the user;
- b) behavior on the part of the user not complying with the established regulations;
- c) actions done by the user in the use of the trademark resulting in cases of criminal offence or infractions.

# Principles of the ESAOTE Policy

# on interactions with Healthcare Organizations and Healthcare Professionals

The interaction between all Group Companies and Healthcare Professionals/Healthcare Organisations is an important feature in achieving mission to make safe, innovative and reliable technology and related services available to more people. The development of innovative medical devices and technologies and the improvement of existing products require collaboration with Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services. The safe and effective use of medical technology and related services requires to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support. The support of medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction all Group Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the relationship.

For such purpose, the following **ten general principles** must always be abided in any case of interaction with Healthcare Professionals/Healthcare Organisations:

- 1. All the interactions must be transparent and comply with national and local laws, regulations or professional codes of conduct.
- 2. Interaction with Healthcare Professionals/Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of our products.
- 3. All the materials and information shared with Healthcare Professionals/Healthcare Organisations must be accurate, balanced, fair, objective, complete, not misleading and be substantiated by the appropriate evidence.
- 4. Never provide, offer or promise anything of value to improperly influence a decision affecting any of our business, including any decision regarding the purchase and supply of our products.

Anything provided of value must be given without expectation of reciprocity, explicit or implied obligation, favour, or action in return.

- 5. Always consider and resolve any potential conflict of interest which has been identified in interactions with Healthcare Professionals/Healthcare Organisations. A conflict is any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision.
- 6. There must always be a real, genuine and legitimate business need for our interactions with Healthcare Professionals/Healthcare Organisations.
- 7. Anything provided of value must be appropriate in the circumstances, be reasonable in value when measured by local market conditions and must be infrequent when combined with all types of benefits (for example, fees for service and hospitality) provided cumulatively. The assessment of whether the benefits are infrequent, must be made on a case by case basis. To determine frequency, we need to assess whether the additional benefit (when combined with all previous benefits provided, usually within a 12 month

period) might undermine the independence, and/or improperly influence the decision making, of the recipient for the benefit of our business. Any fee for service must not exceed the fair market value of the services provided.

- 8. Anything provided of value must be given openly and transparently and must be accurately recorded in our books and records. It must be provided in a manner that would not result in adverse reputational impact or embarrassment to us if publicly disclosed.
- 9. All payments to Healthcare Professionals/Healthcare Organisations must be publicly disclosed where required under applicable law and industry standard to which we adhere.
- 10. For interactions with Healthcare Professionals/Healthcare Organisations, such as where services are performed by a Healthcare Professional for or on behalf of us, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Company.

# INFORMATION NOTICE PURSUANT TO ART. 13 OF THE REGULATION (EU) 2016/679 AND TO THE APPLICABLE LAWS AND REGULATIONS

**1.** Pursuant to the General Data Protection Regulation (hereinafter "GDPR") and to the applicable laws and regulations, ESAOTE S.p.A., with legal address in Genoa (Italy), Via Enrico Melen, 77, (hereinafter, "the company") as a Data Controller of the HCO personal data and in the capacity of legal representative, hereby informs the HCO regarding the processing of its personal data.

# 2. Processing purposes.

The HCO personal data and, where appropriate, its relatives' personal data may be processed in relation to the activities carried out by the company for the following purposes:

- a) fulfilment of legal and regulatory requirements. The provision of the HCO personal information is mandatory to pursue this purpose and an explicit consent is not required.
- b) fulfilment of purposes strictly related to the management and the execution of the contract. The provision of the HCO personal information is discretionary, anyway a refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described in the contract to which the privacy notice is attached.
- c) functional to Esaote activities:
- promotion and selling of Esaote's products or services (executed through the provision of commercial information related to economic, administrative and commercial activities of the Company via phone, mail, carriers, fax, e-mail and through the private area of our website.
- performance of surveys to assess the satisfaction of the customers through interviews or questionnaires;
- processing of studies and market researches performed by Esaote via interviews or questionnaires.

Such processing activities will not involve special categories of personal data.

# 3. Processing legal grounds.

The processing of the HCO personal data carried out by the company, as detailed for the purposes a) and b), is necessary to execute the obligations arising from the present contract. The legal ground to perform the activities detailed at the purpose c) is the HCO explicit consent.

# 4. Processing methods.

In relation with the abovementioned purposes, data are processed either manually (processing of documents and paper documents) and/or with computer methods and procedures, only for the purposes for which they were collected and ensuring data security and confidentiality according to what defined in the policies that transpose the applicable legislation.

Data processing shall be carried out within the scope and with the arrangements envisaged by the Data Protection Authority and includes data collection, recording, retention, rectification, communication, erasure, diffusion, etc.

# 5. Obligatory nature of providing the requested data.

The provision of the HCO personal information is mandatory, with regards to the purpose a), and discretionary, with regards to the purposes b) and c).

A refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described at the purpose b), and thus to perform the contractual relationship. The consent for the activities detailed at the purpose c) is mandatory.

#### 6. Transfer of personal data to countries outside the European Union

The data might be processed by other companies of the Esaote Group, which are also based in non-EU countries whose level of data protection has been considered adequate by the European Commission pursuant to art. 45 of the GDPR, or after signing the Standard Contractual Clauses adopted or approved by the European Commission pursuant to art. 46(2)(c) of the GDPR.

A copy of the guarantees may be requested by contacting the data controller at the email address privacy.esaote@esaote.com

# 7. Data retention.

The HCO data will be processed and kept for no longer than is necessary for the purposes for which data are collected. The HCO personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes and for a time defined by law.

With regards to the purpose c), the HCO data will be maintained in a specific database no longer than 10 years.

# 8. Communication and disclosure of personal data

The HCO personal data may be communicated to Public Authorities, pursuant legal obligations, and to external parties involved in the execution of the purposes detailed above, with specific detail to:

- welfare and social services;
- advisors, partners and freelances;
- companies of Esaote Group;
- banks and/or credit institutions;
- insurance institutions.

Data will not be communicated to other parties, nor will be disclosed without your express consent.

# 9. Data subjects' rights.

The Regulation identifies in art. 15-22 distinct rights that the data subject can exercise against the data controller. These rights are right of access to personal data, right to rectification, to erasure, right to restriction of processing, right to data portability, right to object, right to lodge a complaint to the Authority.

Requests should be sent to: privacy.esaote@esaote.com

# 10. Data controller.

The Data Controller is Esaote S.p.A., with legal address via Enrico Melen 77, 16152 Genova, Italia. Our employees and staff are authorized to process personal data in relation to their tasks, roles and responsibilities. Thus, they have the right to process the HCO personal data within the limits of their competences and pursuant to the instructions given by the data controller.

# 11. Data Protection Officer (DPO)

The Data Protection Officer is Gabriele Faggioli and his contact references are: dpo.esaote@esaote.com.

# Anonymization of personal and special patient data

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# 1. Purpose

The aim of these instructions is to describe how to anonymise personal and special patient data, as required in particular by the document "Rules for the processing of personal data and special data during R&D activities", that gives the instructions to which the R&D personnel must scrupulously comply, in order to correctly process personal and particular patient data in accordance with the European Regulation (EU) 2016/679 of 27 April 2016 on the protection of personal data (GDPR).

# 2. Applicability

These instructions apply to the following cases:

- Exams acquired by the Esaote MRI systems.
- Exams acquired by the Esaote U/S systems.
- Exams acquired by Esaote or other systems and exported in DICOM format.

# 3. General concepts

Anonymisation, that is de-identification of the exams, is required to avoid exposing personal data and special data, as described by GDPR, to any data breach, while maintaining the capability to use them for R&D, marketing and service purposes.

The de-identification algorithms implemented in the Esaote MRI and ultrasound systems have been designed with the aim to avoid that the de-identified exams can be referred to the original patients. In any case, any anonymisation process is always subject to flaws, and some apparently irrelevant information that remains on the header of the images, or on the pixels themselves (for example, text comments) could make possible, in very particular cases, the identification of the physical person the exam belongs to. For this reason the Esaote personnel has to verify carefully that the anonymisation process is safe enough for the particular exams they are applying it.

In case for any reason the anonymisation cannot be applied, or cannot be safe enough, you need to reduce the number of exported images to the minimum necessary, use when possible an encrypted USB pen drive or an encrypted export, delete them as soon as they are not necessary anymore, and carefully scrub the USB pen drive, or destroy the CD-R used to export the original data before the anonymisation.

# 4. Anonymisation from Esaote MRI systems

# 4.1 Anonymisation when exporting

On the current systems, when you need to de-identify one or more exams when exporting them, the following procedure must be used.

From Opi Patient Tree Tab, select the Patient, Study o Series to export de-identified. Choose from the Tools menu, "Service->Export to device..." item.



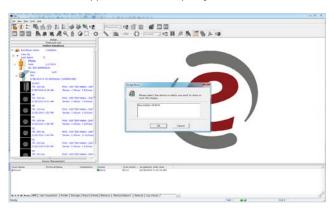
Confirm when asked, that you want to export to DICOM Media:



The de-identification process starts:



At the end, the application asks to specify the device to which de-identified images shall be copied:



# 4.2 Legacy systems

If the exams are contained in a system running a software release that does not support the above procedure, you need to export them in DICOM, and then to anonymise the exported data as described in the chapter 6. Do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

# 5. Anonymisation from Esaote ultrasound systems

The exams contained in the internal database of the Esaote ultrasound systems can be anonymised using the procedure described in the following paragraph 5.1, when possible.

Otherwise you can anonymise the exams by exporting them in Multimedia format (AVI, BMP, JPG etc.), see the following paragraph 5.2.

To get the complete de-identification of the exams exported in Native format see the following paragraph 5.3.

To get the complete de-identification of the exams exported in DICOM format see the chapter 6.

# 5.1 Local anonymisation

On some of the current systems, when you need to de-identify one exam leaving it in the local database, the following procedure can be used.

Select the exam to anonymise, open it, press Patient ID and in the panel press the "Anonymize" button. The patient data are immediately de-identified.

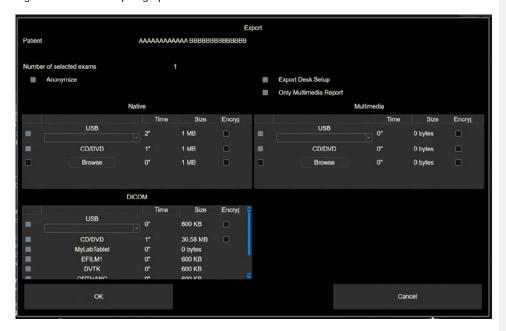


In case the above button is not available, export the exam(s) using the procedure described at paragraph 5.3 and remove them from the local database.

# 5.2 Multimedia anonymisation

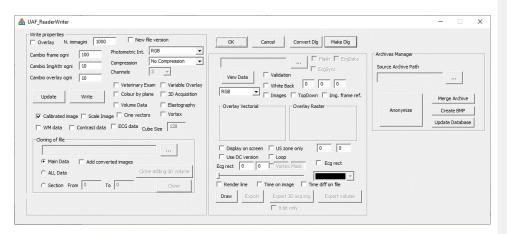
When you need to de-identify one exam exporting it in multimedia format (AVI, BMP, JPG etc.), the following procedure must be used.

Select the exams to anonymise, press Export, and from the Patient ID panel press the "Anonymize" button. The patient data are exported in the selected format(s) using the same algorithm used in the paragraph 0.



# 5.3 Native format anonymisation

The complete anonymisation of one or more exams exported in Native format can be done using the software "UAF Reader/Writer", provided by Esaote as P/N SWE000993. You need to obtain the latest release, to install it in you personal computer (running Windows 10) and to launch it. The following panel appears:



In the "Archives manager" section select, for "Source Archive Path", the folder where the exported database is stored, and press "Anonymize": the exported database will be fully anonymised, so you can import it in a compatible Esaote ultrasound system, using the Database rebuild function.

After the anonymisation, do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

# 6. Anonymisation of DICOM exams

Anonymisation of DICOM exams (exported from any Esaote system) should be performed using the tool DicomCleaner. It is a free open source tool with a user interface for importing, "cleaning" and saving sets of DICOM instances (files); it has been designed by David Clunie, one of the major DICOM experts in the world, and is produced by his company, PixelMed. The tool can be freely downloaded from

 $\underline{http://www.dclunie.com/pixelmed/software/webstart/DicomCleanerUsage.html}$ 

where you can also find all the needed information about its usage. The tool can also blank pixel areas that contain personal information.

After the anonymisation, do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

# 7. Annexes

Not Applicable

# 8. Revision info

First issue

# COLLABORATION (AND LOAN FOR USE) AGREEMENT WITH HEALTHCARE ORGANIZATION (HCO)

- This standard is attached to Esaote Group Key Opinion Leaders Guidelines;
- This standard is ruled under Italian Law;
- The responsibility of ensuring localization of this standard under local applicable laws stays within the relevant company in Esaote Group;
- The same standard applies for:
  - R&D;
- The function initiating the process is responsible for defining the exact and appropriate scope of work of the Agreement.

This page is merely explanatory and must be removed from the agreement draft.

# COLLABORATION (AND LOAN FOR USE) AGREEMENT

# **BETWEEN**

ESAOTE S.p.A., with headquarters in Via Enrico Melen, 77 - 16152, Genoa, Italy, Taxpayer Identification and VAT Code No. 05131180969, hereinafter simply referred to as **ESAOTE**, represented by its Representative [•], endowed with the necessary powers,

# AND

[•], hereinafter simply referred to as Healthcare Organization ("HCO")

# WHEREAS

- The HCO has several years of international experience in the field of diagnosis and therapy at high and medium intensity of care and propose to ESAOTE an agreement to loan for use ESAOTE equipment for specific scientific purposes for improving health.
- ESAOTE has for years been engaged in the development of innovative ultrasound technology with high spatial resolution, MRIs, and diagnosis support clinical software, focusing on specific pathologies.
- ESAOTE is interested in collaborating with the HCO, making available its knowledge
  and equipment, on a temporary basis and under the conditions herein laid out, to the
  collaboration activities herein agreed.
- 4. ESAOTE holds, and shall continue to hold for the entire duration of this Agreement, all the authorizations and licenses necessary to own full rights over the trademark (word and figurative) reproduced in Attachment 3 (hereinafter the "Trademark"), and to grant rights under this Agreement. ESAOTE wishes to promote its products, business, and image, within the territory, in compliance with its ethical principles;
- Also pursuant to Anac resolution n° 831/2016, the Parties specifically declare and acknowledge that no compensation shall be granted to ESAOTE pursuant to this Agreement and ESAOTE will loan the use of the equipment free of charge.

# THE PARTIES THEREFORE AGREE AND COVENANT AS FOLLOWS

# Article 1 - Recitals

The Recitals are an integral and substantive part to this Agreement.

# Article 2 - Object

By this Agreement the Parties agree to carry out collaborative activities in the following areas, as further detailed below ("Activities"):

- 1. Teaching/Training
- 2. Collection of environmental videos and pictures
- 3. Collection of clinical images and clips
- 4. Development of White Papers, Promotional Material, Interviews
- 5. Test (post CE marking) connected with the IQ Software release

#### Article 3 - Performance of the Activities

The Activities shall be carried out as detailed in Attachment 2 herein.

The HCO represents and warrants to have completed all the necessary procedures and to have obtained all the necessary authorizations to sign and perform this Agreement in compliance with the applicable laws and regulations.

# **Article 4 - Activities of the Institution**

The HCO agrees to:

- Indicate, in every type of documentation produced, that the activities have been carried out with ESAOTE equipment.
- Maintain appropriate records in relation to the provision of the Equipment by ESAOTE, including proof of receipt for any Equipment delivered by ESAOTE and proof of delivery of any Equipment returned to ESAOTE.
- 3. Provide the following reports within the timeframes indicated below:

Frequency	Report
6 months	- Semiannual report, calculated starting
	on the date of validity of this
	Agreement.
	- Final Report on the performance of the
	Activities.

4. Enable the members of staff of ESAOTE, as previously communicated by ESAOTE, to carry out jointly agreed visits for the purpose of assisting in the Activities and reaching the objectives detailed under Attachment 2 hereto.

# Article 5 - Loan for Use

For the purpose of assisting in the Activities, ESAOTE makes available to the HCO, under a free-of-charge Loan for Use, one piece of equipment, with CE marking, in compliance with the European directive on medical devices, and described in Attachment 1 herein ("Equipment"), and agrees to provide introductory training for the purpose of using the Equipment to the doctors who shall make use thereof, with the expected duration of 1 (one) week. The Equipment shall be placed within the facilities of the HCO and shall be used with care and diligence. The HCO shall abstain from any use of the Equipment other than those expressly granted under this Agreement and/or necessary to perform the Activities.

The HCO shall bear any costs connected with the use of the Equipment. For the entire duration of this Agreement ESAOTE shall bear all the costs relative to an insurance policy covering against fire and theft, and to the ordinary and extraordinary maintenance of the Equipment. Consumables are expressly excluded.

The HCO shall be held liable for any loss and/or damage to the Equipment caused by the negligence of the users, for any reason whatsoever.

The HCO expressly indemnifies and holds ESAOTE harmless form any liability for damages to persons of things deriving from the use of the Equipment, unless said damages are caused by flaws and/or design and/or manufacturing defects. Pursuant to and by effect of Article 1806 of the Civil Code, any damage or loss of the Equipment will be charged to the HCO, also in the event that such damage or loss is due to unforeseeable circumstances or is not attributable to the HCO. To this effect, the Parties estimate the total value of the Equipment in [•]. Upon termination of this Agreement, ESAOTE shall remove the Equipment at its sole care and expense.

Article 6 - Confidentiality

- The HCO guarantees that the staff appointed to carrying out the Activities shall
  maintain, towards any non-authorized person, full confidentiality as regards to
  any information, knowledge on the performance and the status of the
  Equipment, as well as to any confidential document they may become aware of
  within the scope of this Agreement or any future agreement and/or protocol.
- 2. The HCO agrees to treat as confidential and not to disclose, either directly or indirectly, any information concerning ESAOTE and the products designed by the latter, of which they may gain knowledge during the performance of the Activities. Specifically, the HCO acknowledges that such information shall be deemed property of ESAOTE, and agrees:

Commentato [OF1]: PLEASE SPECIFY

- to keep said information as confidential, and disclose it exclusively to members of staff of the HCO limited to what is strictly necessary for the purpose of performing the Activities, demanding the strictest confidentiality.
- not to copy, disassemble, or in any way interfere with the hardware and the software of ESAOTE S.p.A.'s Equipment.
- if required by ESAOTE, promptly return every piece of written information and any copy thereof.
- This confidentiality agreement does not apply to any information already in the public domain or which was available to the HCO at a time prior to the signing of this Agreement.
- 4. This confidentiality agreement is binding for the duration of this Agreement and for a period of five (5) years after the termination thereof.

# Article 7 - Obligation of the HCO and use of the trademark

- ESAOTE grants to the HCO the right to use the Trademark, exclusively in the measure in which the use of the Trademark is necessary to the HCO to carry out the Activities, for the duration and under the condition laid out in this Agreement.
- 2. The HCO shall be entitled to no right to use the Trademark other than those expressly granted herein. In particular, the HCO shall not have the right to transfer and/or grant in any way to any third party the right to use the Trademark, and undertakes to abstain from any conduct and/or from promoting any initiative connected to the Trademark, and, in any case, to the image of ESAOTE, other than those expressly provided under this Agreement, or which may damage in any way the Trademark or the image of ESAOTE.
- 3. The Parties acknowledge and agree that, at any time during the duration of this Agreement, ESAOTE may request the HCO, via written communication, to cease to use the Trademark, or to use a modified or different mark (the "Modified Trademark"), which shall be communicated by the HCO in the same manner.

The HCO shall cease to use the Trademark upon receipt of ESAOTE's request, and shall refrain from using the Trademark until receipt of a written communication from ESAOTE requesting otherwise. Should ESAOTE request the HCO to use the Modified Trademark, the HCO shall use the Modified Trademark as soon as reasonably possible, and, in any case, no later than a

month after receipt of the notification from ESAOTE. In this case, the costs and expenses required to promptly use the Modified Trademark shall be borne by ESAOTE, by reimbursing the HCO promptly upon receipt of a suitable written evidence of said costs and expenses and a relative invoice.

# Article 8 - Persons in Charge of the Collaboration

Person in charge of the Activities for ESAOTE: the project head appointed by ESAOTE to interact with the HCO shall be [•], who shall liaise with the HCO for anything relating to the performance of the collaboration and of this Agreement.

Person in charge of the activities for the HCO: the scientific project head of the collaboration, and person in charge appointed by the HCO to interact with ESAOTE shall be, [•], who shall liaise with ESAOTE for anything relating to this Agreement, and more specifically, within the scope of the Agreement, sign any formal instrument (report, document, or correspondence).

ESAOTE and the HCO agree to promptly notify in writing the other Party of any variation to the above persons appointed.

The persons appointed for the purpose of the collaboration shall be in charge of organizing one or more training and briefing meetings with ESAOTE's staff on the activities carried out and the results achieved.

# Article 9 - Duration

This Agreement shall be valid from [●] until [●]. Tacit renewal is expressly excluded.

# Article 10 - Compliance with law and policies

The HCO shall perform the Agreement and shall conduct all the Activities in compliance with applicable laws, regulations and professional codes of conduct (including the Assobiomedica code of conduct and COCIR principles).

The management of any relationship and activity involving healthcare professionals who operate for the HCO is under the exclusive responsability of the HCO, including any compensation due or paid to such professionals.

The HCO acknowledges and confirm that Loan for Use of the Equipment does not improperly reward, induce and/or encourage the HCO and/or any HCO's directors, officer or employee to purchase, lease, recommend, use, supply or procure any ESAOTE's product or service.

In any case the HCO shall conduct the Activities in a manner to avoid and, in case, to promptly disclose and resolve any Conflict of Interest which may arise in the interactions between the Parties and/or their directors and officers. For the purpose of this clause "Conflict of Interest" means any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision.

The HCO acknowledges that ESAOTE adopted: (i) a Code of Conduct, (ii) an Organization, Management and Control Model in compliance with Legislative Decree No. 231 of 2001, and (iii) a policy regulating the interactions with Healthcare Organizations and Healthcare Professionals whose principles are here attached under "4" (the "Policy"). The provisions of the Code of Conduct and the Organization, Management, and Control Model can be found on the website <a href="www.esaote.com">www.esaote.com</a>, and constitute an integral and substantive part to this Agreement.

In the performance of the Activities herein set out the HCO agrees to adhere to and comply with ESAOTE's Code of Conduct, the Organization, Management, and Control Model and the Policy, insofar as they are applicable to the HCO, and thus, by signing this Agreement, the HCO also agrees to comply with the provisions therein contained.

In case of violation by the HCO of any obligation set forth under this clause, ESAOTE shall be entitled, pursuant to Article 1456 of the Italian Civil Code, to terminate this Agreement for all purposes of law, and to bring action against the HCO to claim compensation of the relative damages.

# Article 11 - Hygiene and Safety in the Workplace - Mutual Disclosure on Specific Risks and Management of Risks from Interferences

 ESAOTE guarantees full compliance with the obligations provided under Legislative Decree 81/08, as amended, for the purpose of protection of the health and safety of its workers in the work place.

Should ESAOTE's staff, in line with the times and as provided in this Agreement, occasionally visit in work environments under the legal control of the HCO, including in areas featuring risks other than those specifically assessed by ESAOTE, the latter undertakes to provide to the HCO all the necessary and sufficient information on the risks connected with ESAOTE's activities, for the purpose of enabling the HCO to analyze possible interferences between works. ESAOTE agrees to provide its full collaboration necessary to such end.

2. In the performance of the activities herein agreed, the HCO agrees to keep ESAOTE informed of the risks present in the areas where ESAOTE's members of staff may operate, promoting a full cooperation and coordination activity, and the drafting of a Single Document for the Assessment of Interference Risks (*Documento Unico di Valutazione dei Rischi da Interferenza, or DUVRI*) pursuant to Article 26 of Legislative Decree 81/08, as amended, which is to be deemed an integral and substantive part to this Agreement.

# Article 12 - Personal Data Processing

By executing this Agreement the HCO, acknowledges to be Data Owner of the data collected, registered, organized and saved in the memory of the Equipment.

In the event that ESAOTE, during the performance of this Agreement carries out any activity relating to the processing of data pursuant to art. 4, par. 2) of the European Regulation 679/2016 - GDPR, the HCO undertakes to promptly appoint ESAOTE as External Processor pursuant to art. 28 of the above mentioned European Regulation, under the following conditions:

# Data processor shall:

- a) process Personal Data in accordance with and for the specific purposes of the performance of Technical Service Activities and pursuant to the Information Notice attached to the General Terms and Conditions
- b) maintain the highest level of confidentiality about the Personal Data;
- ensure that people authorized to the processing of Personal Data under the authority of the Data Processor is bounded to the duty of confidentiality;
- train people authorized to process Personal Data under the authority of the Data Processor and provide them with adequate instructions relating to data processing activities, monitoring the compliance;
- e) ensure that adequate technical and organizational measures are implemented to ensure a level of security appropriate to the risk, in accordance with Art. 32 of GDPR;
- f) assist the Data Controller, to the extent applicable, in the execution of the Data Protection Impact Assessment and prior consultation, in accordance with Art. 35 and 36 of the Regulation;
- appoint System Administrators and monitor their activity in compliance with the Provision issued by the Data Protection Authority on November 27, 2008 (and subsequent amendments and additions);
- h) promptly both communicate to the Data Controller criticalities and flaws concerning data protection and indicate whether any instructions received by the Data Controller, in its opinion, violates the GDPR or other provisions relating to data protection;
- i) inform the Data Controller about investigations carried out by the Data Protection Authority or any other Authority that involve Personal Data;
- j) notify the Data Controller any Personal Data breach likely to result in a risk to the rights and freedoms of the data subjects, according to the manner and providing all the information pursuant to art. 33 of the GDPR and supporting the Data Controller for the consequent communications to the data subjects referred to in art. 34 of the GDPR;

- k) keep a written record of the processing activities carried out on behalf of the Data Controller pursuant to art. 30 of the Regulation provide to the Data Controller a report showing the status of the activities carried and the measures put in place to comply with GDPR pursuant to art. 30 of the GDPR;
- when the Data Processor needs to transfer Personal Data to a third country or an international organization in compliance with Union or Member State law, it informs the Data Controller of this legal requirement before processing, unless that law prohibits such information on important grounds of public interest;
- m) for the purposes of processing Personal Data for the purposes under letter a) above, in the case where the Data processor intends to make use of Sub-Processors or in the case where any information provided to the Data Controller is to be updated or amended, the Data Processor shall previously inform the Data Controller including the identity, contact details and the relevant activities carried out by the Sub-processors. In case the Data Controller does not make opposition within 5 days from the notification by the data processor, the use of the sub-contractor and appointment of sub-processor shall be authorized.
  - In case of the appointment of Sub-Processor, the Data Processor shall impose on the same the obligations set out in these Conditions. If, furthermore, the Sub-Processor fails to comply with its data protection obligations, the Data Processor retains the entire responsibility for the fulfillment of the obligations of the other party towards the Data Controller.
- n) delete or return all the personal data after the end of the provision of services relating to the processing and delete existing copies, unless Union or Member State law requires storage of the personal data;
- o) make available to the Data Controller all the information necessary to demonstrate compliance with the obligations referred to in this appointment letter and allow and contribute to the review activities, including inspections, carried out by the data controller or another person appointed by them.

ESAOTE will process the HCO personal data as per the Information Notice here attached under "5".

In addition to the above, at the termination of this Agreement, the HCO undertakes to return the Equipment without any data ownership of which is of the HCO.

It remains understood that ESAOTE will have the right to receive data anonymized according to ESAOTE Procedure here attached under "6" regarding data subjects collected and/or anyhow processed ny means of the System.

ESAOTE will be therefore authorized to freely use anonymized data received and/or obtained as described above in order to improve ESAOTE products and/or services and/or to develop new products and/or services with no obligation to grant anything to the HCO for any reason whatsoever.

To this effect, the HCO declares and acknowledges that ESAOTE anonymization process is legitimate as well as the subsequent use of anonymized data for the abovementioned purposes.

The HCO also declares and guarantees to have all necessary authorizations and consents for for processing personal data to the effect of this Contract.

The HCO undertakes to release ESAOTE from any consequence, loss of action, even carried out by third parties, deriving from the violation by the HCO of the declarations and warranties here described.

# Article 13 - Intellectual Property Rights

For the purpose of this clause:

"New IPR" shall mean all IPR that may be developed during the term of this Agreement, directly or indirectly, in the performance of, or in connection with, the performance of this Agreement, whether based on ESAOTE Background IPR, whether based on HCO Background IPR, or whether jointly developed or developed independently by either party. "Intellectual Property Rights" or "IPR" shall mean all legal protection throughout the world recognized by law (whether by statute, common law or otherwise) with respect to intellectual property, including:

- all trademarks (registered and unregistered), applications, registrations, and renewals in connection therewith, service marks, trade dress, logos, trade names, Internet domain names, fictional business names and corporate names, together with all translations, adaptations, derivations, and combinations thereof and including all goodwill associated therewith (collectively, "Marks");
- 2) all industrial designs, inventions and discoveries (whether patentable or unpatentable and whether or not reduced to practice), all improvements thereto, and all patents, patent applications, statutory invention registrations, provisional patent applications and patent disclosures, together with all reissuances, continuations, continuations-inpart, divisionals, revisions, extensions, and reexaminations thereof (collectively, "Patents");
- all copyrightable works, all copyrights in both published works and unpublished works, and all applications, registrations, and renewals in connection therewith (collectively, "Copyrights");
- 4) all rights in mask works and all applications, registrations, and renewals in connection therewith (collectively, "Rights in Mask Works") and
- 5) all know-how, trade secrets and confidential information (including ideas, research and development, formulas, compositions, manufacturing and production processes and techniques, technical information, data, process technology, plans, designs, drawings, specifications, blue prints, customer and supplier lists, pricing and cost information, and

business and marketing plans and proposals), all Software (including data and related documentation), all other proprietary rights, and all copies and tangible embodiments thereof, in whatever form or medium (collectively, "Trade Secrets").

"<u>HCO Background IPR</u>" shall mean an Intellectual Property Rights developed by, under control, of, or otherwise owned by HCO before the effective date of this Agreement.

"ESAOTE Background IPR" shall mean an Intellectual Property Rights developed by, under control, of, or otherwise owned by ESAOTE before the effective date of this Agreement.

ESAOTE retains complete ownership of all Intellectual Property Rights in and to the ESAOTE Background IPR.

ESAOTE shall have sole ownership of any and all New IPR.

HCO agrees to and does hereby assign all right, title and interest in and to all New IPR to ESAOTE.

HCO shall not have the right to make, have made, reproduce, make derivative works from, use, license, lease, sell, market, display, disclose, perform, distribute, import or export products embodying, utilizing or produced through the use of any New IPR or otherwise license to third parties any New IPR, without the prior written consent of ESAOTE.

# Article 14 - Governing Law and Jurisdiction

This Agreement is governed under the laws of the Republic of Italy.

Any dispute arising out of or in connection to the interpretation or performance of this Agreement shall be subject to the exclusive jurisdiction of the Court of Genoa, Italy.

Read, confirmed, and signed		
For the HCO		
For ESAOTE		
	_	

Description of the equipment object to this Agreement as per point 5.

Code	Description
[•]	[•]
	Add Probes or Other

# Description of the Activities

# Teaching/Training:

Description of the Activity: <fill in according to the activity> Course of Action: <fill in according to the activity> Expected Results: <fill in according to the activity>

# Collection of Environmental Video and Pictures

Course of Action: <fill in according to the activity> Expected Results: <fill in according to the activity>

# Collection of Clinical Images and Clips:

Expected Results: <fill in according to the activity>
The HCO agrees to provide to ESAOTE the data and images collected, in anonymous form and in any case in the respect of the patients' privacy.

# Development of Promotional Material, including White Papers and Interviews:

Expected Results: <fill in according to the activity>

# Tests (post CE marking) connected with the IQ Software release:

Description of the Activity: <fill in according to the activity>
Course of Action: <fill in according to the activity>
Expected Results: <fill in according to the activity>

# COMPANY TRADEMARK AND TRADEMARK USE REGULATION

#### TRADEMARK



# RULES FOR THE OCCASIONAL AND TEMPORARY USE OF THE ESAOTE TRADEMARK

# SECTION 1. - LEGAL OWNERSHIP AND DESIGNATION OF THE TRADEMARK

Esaote is the legal owner of the trademark described in section No. 2 of these rules. Individuals who are granted authorization to make occasional and temporary use of the Trademark expressly recognize that Esaote is the sole legal owner of the Trademark; moreover, they recognize the value and goodwill associated with the trademarks and acknowledge that value and goodwill belong exclusively to Esaote. They further recognize that the right to use the Trademark must be exercised in strict obedience to the conditions and Terms of these rules, and that they will not at any time or in any way acquire any further rights to the trademark, under its use in the forms authorized by Esaote.

# SECTION 2. - DESCRIPTION OF THE TRADEMARK

The trademark



corresponds to the characteristics described in document No. MAK000115 Ver. 01 "Corporate Identity - The new guidelines for the use of the Esaote Trademark and its applications".

# SECTION 3. - PURPOSES AND AIMS OF THE TRADEMARK

By means of the Trademark, Esaote intends to pursue the following goals:

- to promote the corporate image;
- to identify technologies, activities, and services generated by the Company;
- to enhance less invasive, more accessible methods of diagnostic imaging, offering, at the same time, higher efficiency standards, such as those developed by Esaote;
- to spread the values of creativity, innovation, and excellence in research and development that are particular to the Company's story.

For these key reasons, the trademark must be protected and safeguarded.

#### SECTION 4. OWNERSHIP OF THE TRADEMARK

The Trademark is owned exclusively by Esaote SpA.

Only Esaote has the right to authorize the use of the Trademark by third parties who so request it, specifying the terms, methods and limits of that use.

#### SECTION 5. USE OF THE TRADEMARK

Individuals who are granted authorization to make temporary and occasional use of the Trademark undertake:

- to not use the Trademark in any way, not even through a third person, if it is not included in the ways provided by these Rules, by the manual "Guidelines for the use of the Esaote Trademark" or, anyhow, by the forms specifically established at the moment of authorization;
- to not use in any way, even through a third person, distinguishing images, other images, words, or names that are similar to and/or may be confused with the Trademark;
- to not register trademarks or domain names in their own name that incorporate the words, letters, writing, images or colors that characterize the Trademark, nor any trademark that could be confused with that of Esaote or that is based on it or that could be considered derived from it in any way;
- to not make any sort of variation, addition, or graphic, chromatic or literal modification to the trademark, that is, to not use the trademark in connection, combination, or together with other trademarks, names, words, images, symbols, or colors without prior written approval from Esaote;
- to not depict, display, or promote together with the depiction of the Trademark, trademarks referring to or products made by Esaote's competitors;
- to not sub-grant, transfer, or authorize use of the Trademark to third parties, as that use must only be made directly by the individuals authorized by Esaote;
- to not grant to third parties in sub-license or to any other titles the right or power to use the Trademark, even only partially, as granted by Esaote.

Esaote reserves the right to demand suspension of all forms of the Trademark's use at any time, when that use is not made in compliance with the conditions here defined.

Consequently, the user cannot make partial use of the Trademark nor modify it in any way, but must use it in its entirety, and in the shapes, dimensions, graphic depiction, and colors as provided by the manual "Guidelines for the use of the Esaote Trademark", or in any case, in the forms specifically established at the moment of authorization. The Guidelines' duration is unlimited.

# SECTION 6. DURATION OF THE AUTHORIZATION

The duration of the right to use the Trademark will be determined at the time of authorization, with expiration of all rights of use occuring for that defined period without the necessity of any formal correspondence, except in cases of suspension, revocation, forfeiture, or cancellation, in accordance with the methods described in sections 9, 10, and 11 of these rules.

# SECTION 7. TRADEMARK PROTECTION

Use of the trademark for activities in contrast with Esaote's constitutional aims is strictly prohibited.

The user recognizes the trademark's prestige and, consequently, undertakes to use the trademark with the utmost care and diligence. As such, all activities carried out by the user while using the Esaote trademark must be performed in such a way so as not to damage Esaote's image or in any way harm the trademark's reputation. In particular, the user agrees not to use the Trademark in a way that is deceptive toward the public.

The user recognizes that the trademark is the exclusive property of Esaote and agrees to immediately inform the same of any third party action or event that may constitute a real or suspected violation of the rights of Trademark ownership, reporting every objection, complaint, or warning related to the use of the Trademark, as well as any falsification that has come to his/her attention.

The user and Esaote will, therefore, lend each other reciprocal collaboration in every effort meant to protect and defend the trademark, subject to Esaote's full autonomy and discretion in the adoption of measures deemed opportune for the purposes above indicated.

Esaote may carry out inspections, directly or via third parties, to ensure the correct use of the trademark

In accordance with that which is provided by trademark protection law, Esaote has the right to initiate legal proceedings against all those who use the trademark without prior authorization.

#### SECTION 8. NON-AUTHORIZED USE OF THE TRADEMARK

In the case of non-authorized use of the Trademark or use of the Trademark that diverges from the regulations imposed at the time of authorization, Esaote will order immediate cessation of the use, as well as the destruction of all related materials or the interruption of all activities deemed damaging to Esaote's rights, operating in the appropriate central offices for the protection of its rights.

Use of the Trademark by any individual who is not authorized or in divergence with respect to the terms of authorization will be prosecuted by Esaote in accordance with the measures provided by national and international laws for the protection of intellectual property.

#### **SECTION 9. CANCELLATION AND FORFEITURE**

With all other powers of cancellation according to the provisions of the law still holding, noncompliant use of the trademark with respect to the terms and methods established by these Rules, by the Guidelines for the Use of the Esaote Trademark, and by the specific regulations potentially dictated by Esaote at the time of authorization will entail Esaote's right to cancel the

contract pursuant to and in accordance with Art. 1456 of the Italian Civil Code, with the associated automatic rescindment of the authorization.

If Esaote voluntarily ends use of or modifies the Trademark, existing authorizations for the use of the Trademark expire automatically without any expenses charged to Esaote.

In all cases of suspension of the effects of authorization for the use of the Trademark, including expiration, cancellation, and forfeiture, the user is duty bound to immediately cease any activity that involves the use and depiction of the Trademark, and in any case, to cease any distribution of materials in which the Trademark is depicted (such as catalogues, leaflets, labels, websites, or any other communicative material).

#### SECTION 10. REVOCABILITY OF THE AUTHORIZATION

Authorization for the use of the trademark may be unilaterally revoked by Esaote at any time. Anyhow, the contract will be understood as cancelled by operation of law in the case of:

- a) bankruptcy or subjection to other insolvency procedures on the part of the user;
- b) behavior on the part of the user not complying with the established regulations;
- actions done by the user in the use of the trademark resulting in cases of criminal offence or infractions.

#### Principles of the ESAOTE Policy

#### on interactions with Healthcare Organizations and Healthcare Professionals

The interaction between all Group Companies and Healthcare Professionals/Healthcare Organisations is an important feature in achieving mission to make safe, innovative and reliable technology and related services available to more people. The development of innovative medical devices and technologies and the improvement of existing products require collaboration with Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services. The safe and effective use of medical technology and related services requires to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support. The support of medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction all Group Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the relationship.

For such purpose, the following **ten general principles** must always be abided in any case of interaction with Healthcare Professionals/Healthcare Organisations:

- 1. All the interactions must be transparent and comply with national and local laws, regulations or professional codes of conduct.
- 2. Interaction with Healthcare Professionals/Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of our products.
- 3. All the materials and information shared with Healthcare Professionals/Healthcare Organisations must be accurate, balanced, fair, objective, complete, not misleading and be substantiated by the appropriate evidence.
- 4. Never provide, offer or promise anything of value to improperly influence a decision affecting any of our business, including any decision regarding the purchase and supply of our products.

Anything provided of value must be given without expectation of reciprocity, explicit or implied obligation, favour, or action in return.

- 5. Always consider and resolve any potential conflict of interest which has been identified in interactions with Healthcare Professionals/Healthcare Organisations. A conflict is any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision.
- 6. There must always be a real, genuine and legitimate business need for our interactions with Healthcare Professionals/Healthcare Organisations.
- 7. Anything provided of value must be appropriate in the circumstances, be reasonable in value when measured by local market conditions and must be infrequent when combined with all types of benefits (for example, fees for service and hospitality) provided cumulatively. The assessment of whether the benefits are infrequent, must be made on a case by case basis. To determine frequency, we need to assess whether the additional benefit (when combined with all previous benefits provided, usually within a 12 month

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period) might undermine the independence, and/or improperly influence the decision making, of the recipient for the benefit of our business. Any fee for service must not exceed the fair market value of the services provided.

- 8. Anything provided of value must be given openly and transparently and must be accurately recorded in our books and records. It must be provided in a manner that would not result in adverse reputational impact or embarrassment to us if publicly disclosed.
- 9. All payments to Healthcare Professionals/Healthcare Organisations must be publicly disclosed where required under applicable law and industry standard to which we adhere.
- 10. For interactions with Healthcare Professionals/Healthcare Organisations, such as where services are performed by a Healthcare Professional for or on behalf of us, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Company.

## INFORMATION NOTICE PURSUANT TO ART. 13 OF THE REGULATION (EU) 2016/679 AND TO THE APPLICABLE LAWS AND REGULATIONS

**1.** Pursuant to the General Data Protection Regulation (hereinafter "GDPR") and to the applicable laws and regulations, ESAOTE S.p.A., with legal address in Genoa (Italy), Via Enrico Melen, 77, (hereinafter, "the company") as a Data Controller of the HCO personal data and in the capacity of legal representative, hereby informs the HCO regarding the processing of its personal data.

#### 2. Processing purposes.

The HCO personal data and, where appropriate, its relatives' personal data may be processed in relation to the activities carried out by the company for the following purposes:

- fulfilment of legal and regulatory requirements. The provision of the HCO personal information is mandatory to pursue this purpose and an explicit consent is not required.
- b) fulfilment of purposes strictly related to the management and the execution of the contract. The provision of the HCO personal information is discretionary, anyway a refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described in the contract to which the privacy notice is attached.
- c) functional to Esaote activities:
- promotion and selling of Esaote's products or services (executed through the provision of commercial information related to economic, administrative and commercial activities of the Company via phone, mail, carriers, fax, e-mail and through the private area of our website.
- performance of surveys to assess the satisfaction of the customers through interviews or questionnaires;
- processing of studies and market researches performed by Esaote via interviews or questionnaires.

Such processing activities will not involve special categories of personal data.

#### 3. Processing legal grounds.

The processing of the HCO personal data carried out by the company, as detailed for the purposes a) and b), is necessary to execute the obligations arising from the present contract. The legal ground to perform the activities detailed at the purpose c) is the HCO explicit consent.

#### 4. Processing methods.

In relation with the abovementioned purposes, data are processed either manually (processing of documents and paper documents) and/or with computer methods and procedures, only for the purposes for which they were collected and ensuring data security and confidentiality according to what defined in the policies that transpose the applicable legislation.

Data processing shall be carried out within the scope and with the arrangements envisaged by the Data Protection Authority and includes data collection, recording, retention, rectification, communication, erasure, diffusion, etc.

#### 5. Obligatory nature of providing the requested data.

The provision of the HCO personal information is mandatory, with regards to the purpose a), and discretionary, with regards to the purposes b) and c).

A refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described at the purpose b), and thus to perform the contractual relationship. The consent for the activities detailed at the purpose c) is mandatory.

#### 6. Transfer of personal data to countries outside the European Union

The data might be processed by other companies of the Esaote Group, which are also based in non-EU countries whose level of data protection has been considered adequate by the European Commission pursuant to art. 45 of the GDPR, or after signing the Standard Contractual Clauses adopted or approved by the European Commission pursuant to art. 46(2)(c) of the GDPR.

A copy of the guarantees may be requested by contacting the data controller at the email address privacy.esaote@esaote.com

#### 7. Data retention.

The HCO data will be processed and kept for no longer than is necessary for the purposes for which data are collected. The HCO personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes and for a time defined by law.

With regards to the purpose c), the HCO data will be maintained in a specific database no longer than 10 years.

#### 8. Communication and disclosure of personal data

The HCO personal data may be communicated to Public Authorities, pursuant legal obligations, and to external parties involved in the execution of the purposes detailed above, with specific detail to:

- welfare and social services;
- advisors, partners and freelances;
- companies of Esaote Group;
- banks and/or credit institutions;
- insurance institutions.

Data will not be communicated to other parties, nor will be disclosed without your express consent.

#### 9. Data subjects' rights.

The Regulation identifies in art. 15-22 distinct rights that the data subject can exercise against the data controller. These rights are right of access to personal data, right to rectification, to erasure, right to restriction of processing, right to data portability, right to object, right to lodge a complaint to the Authority.

Requests should be sent to: privacy.esaote@esaote.com

#### 10. Data controller.

The Data Controller is Esaote S.p.A., with legal address via Enrico Melen 77, 16152 Genova, Italia. Our employees and staff are authorized to process personal data in relation to their tasks, roles and responsibilities. Thus, they have the right to process the HCO personal data within the limits of their competences and pursuant to the instructions given by the data controller.

#### 11. Data Protection Officer (DPO)

The Data Protection Officer is Gabriele Faggioli and his contact references are: dpo.esaote@esaote.com.

# Anonymization of personal and special patient data

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#### 1. Purpose

The aim of these instructions is to describe how to anonymise personal and special patient data, as required in particular by the document "Rules for the processing of personal data and special data during R&D activities", that gives the instructions to which the R&D personnel must scrupulously comply, in order to correctly process personal and particular patient data in accordance with the European Regulation (EU) 2016/679 of 27 April 2016 on the protection of personal data (GDPR).

## 2. Applicability

These instructions apply to the following cases:

- Exams acquired by the Esaote MRI systems.
- Exams acquired by the Esaote U/S systems.
- Exams acquired by Esaote or other systems and exported in DICOM format.

#### 3. General concepts

Anonymisation, that is de-identification of the exams, is required to avoid exposing personal data and special data, as described by GDPR, to any data breach, while maintaining the capability to use them for R&D, marketing and service purposes.

The de-identification algorithms implemented in the Esaote MRI and ultrasound systems have been designed with the aim to avoid that the de-identified exams can be referred to the original patients. In any case, any anonymisation process is always subject to flaws, and some apparently irrelevant information that remains on the header of the images, or on the pixels themselves (for example, text comments) could make possible, in very particular cases, the identification of the physical person the exam belongs to. For this reason the Esaote personnel has to verify carefully that the anonymisation process is safe enough for the particular exams they are applying it.

In case for any reason the anonymisation cannot be applied, or cannot be safe enough, you need to reduce the number of exported images to the minimum necessary, use when possible an encrypted USB pen drive or an encrypted export, delete them as soon as they are not necessary anymore, and carefully scrub the USB pen drive, or destroy the CD-R used to export the original data before the anonymisation.

## 4. Anonymisation from Esaote MRI systems

## 4.1 Anonymisation when exporting

On the current systems, when you need to de-identify one or more exams when exporting them, the following procedure must be used.

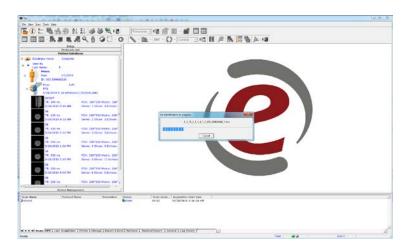
From Opi Patient Tree Tab, select the Patient, Study o Series to export de-identified. Choose from the Tools menu, "Service->Export to device..." item.



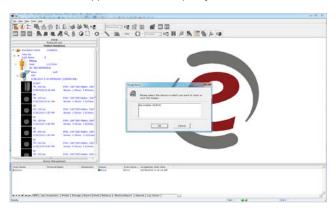
Confirm when asked, that you want to export to DICOM Media:



The de-identification process starts:



At the end, the application asks to specify the device to which de-identified images shall be copied:



## 4.2 Legacy systems

If the exams are contained in a system running a software release that does not support the above procedure, you need to export them in DICOM, and then to anonymise the exported data as described in the chapter 6. Do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

## 5. Anonymisation from Esaote ultrasound systems

The exams contained in the internal database of the Esaote ultrasound systems can be anonymised using the procedure described in the following paragraph 5.1, when possible.

Otherwise you can anonymise the exams by exporting them in Multimedia format (AVI, BMP, JPG etc.), see the following paragraph 5.2.

To get the complete de-identification of the exams exported in Native format see the following paragraph 5.3.

To get the complete de-identification of the exams exported in DICOM format see the chapter 6.

#### 5.1 Local anonymisation

On some of the current systems, when you need to de-identify one exam leaving it in the local database, the following procedure can be used.

Select the exam to anonymise, open it, press Patient ID and in the panel press the "Anonymize" button. The patient data are immediately de-identified.

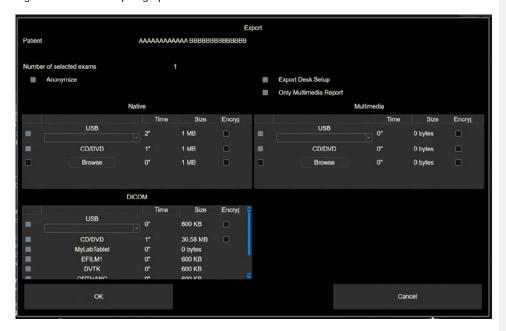


In case the above button is not available, export the exam(s) using the procedure described at paragraph 5.3 and remove them from the local database.

## 5.2 Multimedia anonymisation

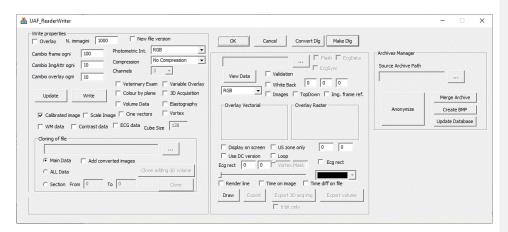
When you need to de-identify one exam exporting it in multimedia format (AVI, BMP, JPG etc.), the following procedure must be used.

Select the exams to anonymise, press Export, and from the Patient ID panel press the "Anonymize" button. The patient data are exported in the selected format(s) using the same algorithm used in the paragraph 0.



## 5.3 Native format anonymisation

The complete anonymisation of one or more exams exported in Native format can be done using the software "UAF Reader/Writer", provided by Esaote as P/N SWE000993. You need to obtain the latest release, to install it in you personal computer (running Windows 10) and to launch it. The following panel appears:



In the "Archives manager" section select, for "Source Archive Path", the folder where the exported database is stored, and press "Anonymize": the exported database will be fully anonymised, so you can import it in a compatible Esaote ultrasound system, using the Database rebuild function.

After the anonymisation, do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

## 6. Anonymisation of DICOM exams

Anonymisation of DICOM exams (exported from any Esaote system) should be performed using the tool DicomCleaner. It is a free open source tool with a user interface for importing, "cleaning" and saving sets of DICOM instances (files); it has been designed by David Clunie, one of the major DICOM experts in the world, and is produced by his company, PixelMed. The tool can be freely downloaded from

 $\underline{http://www.dclunie.com/pixelmed/software/webstart/DicomCleanerUsage.html}$ 

where you can also find all the needed information about its usage. The tool can also blank pixel areas that contain personal information.

After the anonymisation, do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

#### 7. Annexes

Not Applicable

## 8. Revision info

First issue

## COLLABORATION (AND LOAN FOR USE) AGREEMENT WITH HEALTHCARE PROFESSIONAL (HCP)

- This standard is attached to Esaote Group Key Opinion Leaders Guidelines;
- This standard is ruled under Italian Law;
- The responsibility of ensuring localization of this standard under local applicable laws stays within the relevant company in Esaote Group;
- The same standard applies for:
  - Marketing;
- The function initiating the process is responsible for defining the exact and appropriate scope of work of the Agreement.

This page is merely explanatory and must be removed from the agreement draft.

#### COLLABORATION AND LOAN FOR USE AGREEMENT

#### **BETWEEN**

ESAOTE S.p.A., with headquarters in Via Enrico Melen, 77 - 16152, Genoa, Italy, Taxpayer Identification and VAT Code No. 05131180969, hereinafter simply referred to as **ESAOTE**, represented by its Representative [•], endowed with the necessary powers,

#### **AND**

[•] hereinafter simply referred to as **Healthcare Professional** ("HCP")

#### WHEREAS

- ESAOTE has for years been engaged in the development of innovative ultrasound technology with high spatial resolution, MRIs, and diagnosis support clinical software, focusing on specific pathologies.
- ESAOTE is interested in promoting its products, its activities and its image on the territory in compliance with its ethical principles, trough professional doctors who are not part of Esaote's organization and who have appropriate professional compentencies.
- 3. The Healthcare Professional, Dr. [•], specialized in [•], enrolled in the [•] register, has developed a multi-year experience in the field of diagnostics and of medium-high intensity care and considering the specific activities as well as his experience, showed his/her interest and his/her availability to start a collaboration with Esaote by defining autonomously processes, timing and sites to carry out his/her activities.
- In particular, The Healthcare Professional asked ESAOTE to enter into a loan for use of ESAOTE equipment for exclusive scientific purposes and aiming at the best health safeguard.
- 5. ESAOTE is in turn interestested in a collaboration with the Healthcare Professional making ESAOTE equipment temporarily available under the conditions specified below and taking advantage of Healthcare Professional's expertise, competencies, medical and healthcare experiences, as well as of his/her professionality, with a collaboration under art. 2229 of the Italian Civil Code and subject to Healthcare Professional's availability.
- 6. The Parties expressely agree to exclude any subordination relationship.

- 7. ESAOTE holds, and shall continue to hold for the entire duration of this Agreement, all the authorizations and licenses necessary to own full rights over the trademark (word and figurative) reproduced in Attachment 3 (hereinafter the "Trademark"), and to grant rights under this Agreement.
- 8. The Parties agreed to execute this Agreement in order to manage their collaboration. All the above mentioned:

#### THE PARTIES THEREFORE AGREE AND COVENANT AS FOLLOWS

#### Article 1 - Recitals

The Recitals are an integral and substantive part to this Agreement.

#### Article 2 - Object

ESAOTE engags the Healthcare Professional to carry out collaboration activities in the following areas, as further detailed in Attachment [•] and below ("Activities"):

- 1. Teaching/Training
- 2. Collection of environmental videos and pictures
- 3. Collection of clinical images and clips
- 4. Development of White Papers, Promotional Material, Interviews
- $5. \ \ Test \ (post \ CE \ marking) \ connected \ with \ the \ IQ \ Software \ release$

The Activities shall be carried out subject to Healthcare Professional's availability and with the necessary coordination with ESAOTE.

In addition to the above, the Healthcare Professional shall be, subject to his/her availability, carrying out application trainings on MRI systems to ESAOTE customers on the territoty as specified below:

- Application corrective interventions at ESAOTE customers
- Commercial demos on ESAOTE MRI systems
- Presentations of ESAOTE MRI sisystems at ESAOTE study centers as, as an example, MR-Academy.

#### **Article 3 - Performance of the Activities**

The Activities shall be carried out as detailed in Attachment [•] herein.

The Healthcare Professional will be free to organize and manage all aspects and methodologies of the Activities with no duty of presence and/or venue and/or time, different from those relating to the achievement of the best result of the Activities, in complete decisional and operative freedom, except for the necessary coordination with ESAOTE.

The Healthcare Professional, under his/her own responsibility, represents and warrants to have completed all the necessary procedures and to have obtained all the necessary authorizations to sign and perform this Agreement in compliance with the applicable laws and regulations.

The Healthcare Professional, under his own responsibility, also warrants that he/dhe is allowed to carry out the Activities as described under Article 2 and in Attachment [•], pursuant to the law as well as to other applicable regulations applicable both in Italy and abroad.

The Healthcare Professional is available to attend meetings as well as training sessions and to share with ESAOTE all the activities and relevant results, that will be agreed by the Parties on the basis of their respective availability.

#### Article 4 - Activities of the Healthcare Professional

The Healthcare Professional agrees to:

- Indicate, in every type of documentation produced, that the activities have been carried out with ESAOTE equipment.
- Maintain appropriate records in relation to the provision of the Equipment by ESAOTE, including proof of receipt for any Equipment delivered by ESAOTE and proof of delivery of any Equipment returned to ESAOTE.
- 3. Provide the following reports within the timeframes indicated below:

Frequency	Report
6 months	- Semiannual report, calculated starting
	on the date of validity of this
	Agreement.
	Final Report on the performance of the
	activities.

4. Enable the members of staff of ESAOTE, as previously communicated by ESAOTE, to carry out jointly agreed visits for the purpose of assisting in the Activities and reaching the objectives detailed under Attachment [•] hereto.

#### Article 5 - Loan for Use

For the purpose of assisting in the Activities, ESAOTE makes available to the Healthcare Professional, under a free-of-charge Loan for Use, one piece of equipment, with CE marking, in compliance with the European directive on medical devices, and described in Attachment 2 herein ("Equipment"), and agrees to provide introductory training for the purpose of using the Equipment to the doctors who shall make use thereof, with the expected duration of 1 (one) week. The Equipment shall be placed within the facilities of the Healthcare Professional and shall be used with care and diligence. The Healthcare Professional shall abstain from any use of the Equipment other than those expressly granted under this Agreement and/or necessary to perform the Activities.

The Healthcare Professional shall bear any costs connected with the use of the Equipment. For the entire duration of this Agreement ESAOTE shall bear all the costs relative to an insurance policy covering against fire and theft, and to the ordinary and extraordinary maintenance of the Equipment. Consumables are expressly excluded.

The Healthcare Professional shall be held liable for any loss and/or damage to the Equipment caused by the negligence of the users, for any reason whatsoever.

The Healthcare Professional expressly indemnifies and holds ESAOTE harmless form any liability for damages to persons of things deriving from the use of the Equipment, unless said damages are caused by flaws and/or design and/or manufacturing defects. Pursuant to and by effect of Article 1806 of the Civil Code, any damage or loss of the Equipment will be charged to the Healthcare Professional, also in the event that such damage or loss is due to unforeseeable circumstances or is not attributable to the Healthcare Professional. To this effect, the Parties estimate the total value of the Equipment in [•]. Upon termination of this Agreement, ESAOTE shall remove the Equipment at its sole care and expense.

Article 6 - Confidentiality

 The Healthcare Professional guarantees to maintain, towards any person non-authorized by ESAOTE, full confidentiality as regards to any information, knowledge on the performance and the status of the Equipment, as well as to any confidential document they may become aware of within the scope of this Agreement or any future agreement and/or protocol. Commentato [OF1]: specificare

- 2. The Healthcare Professional agrees to treat as confidential and not to disclose, either directly or indirectly, any information concerning ESAOTE and the products designed by the latter, of which they may gain knowledge during the performance of the Activities. Specifically, the Healthcare Professional acknowledges that such information shall be deemed property of ESAOTE, and agrees:
  - to keep said information as confidential and disclose it exclusively to members of staff of the Healthcare Professional limited to what is strictly necessary for the purpose of performing the Activities, demanding the strictest confidentiality.
  - not to copy, disassemble, or in any way interfere with the hardware and the software of ESAOTE S.p.A.'s Equipment.
  - if required by ESAOTE, promptly return every piece of written information and any copy thereof.
- This confidentiality agreement does not apply to any information already in the public domain or which was available to the Healthcare Professional at a time prior to the signing of this Agreement.
- This confidentiality agreement is binding for the duration of this Agreement and for a period of five (5) years after the termination thereof.

#### Article 7 - Obligation of the Healthcare Professional and use of the trademark

- ESAOTE grants to the Healthcare Professional the right to use the Trademark, exclusively
  in the measure in which the use of the Trademark is necessary to the Healthcare
  Professional to carry out the Activities, for the duration and under the condition laid out
  in this Agreement.
- 2. The Healthcare Professional shall be entitled to no right to use the Trademark other than those expressly granted herein. In particular, the Healthcare Professional shall not have the right to transfer and/or grant in any way to any third party the right to use the Trademark, and undertakes to abstain from any conduct and/or from promoting any initiative connected to the Trademark, and, in any case, to the image of ESAOTE, other than those expressly provided under this Agreement, or which may damage in any way the Trademark or the image of ESAOTE.

- 3. The Parties acknowledge and agree that, at any time during the duration of this Agreement, ESAOTE may request the Healthcare Professional, via written communication, to cease to use the Trademark, or to use a modified or different mark (the "Modified Trademark"), which shall be communicated by the Healthcare Professional in the same manner.
- The Healthcare Professional shall cease to use the Trademark upon receipt of ESAOTE's request, and shall refrain from using the Trademark until receipt of a written communication from ESAOTE requesting otherwise. Should ESAOTE request the Healthcare Professional to use the Modified Trademark, the Healthcare Professional shall use the Modified Trademark as soon as reasonably possible, and, in any case, no later than a month after receipt of the notification from ESAOTE. In this case, the costs and expenses required to promptly use the Modified Trademark shall be borne by ESAOTE, by reimbursing the Healthcare Professional promptly upon receipt of a suitable written evidence of said costs and expenses and a relative invoice.

#### Article 8 - Persons in Charge of the Collaboration

Person in charge of the Activities for ESAOTE: the project head appointed by ESAOTE to interact with the Healthcare Professional shall be [•] or any other person delegated by [•], who shall liaise for anything relating to the performance of the collaboration and of this Agreement.

Communications between the Parties shall be via e-mail of registered mail with proof of receipt:

- if to the Company: [●]
- if to the Healthcare Professional: [●]

or to a different address that the Parties can communicate each other after the date of execution of this Agreement and being agreed that the Parties choose as their domicile for any purposes of this Agreement the addresses indicated above or successively communicated.

#### Article 9 - Duration

This Agreement shall be valid from [●] until [●]. Tacit renewal is expressly excluded.

The Healthcare Professional shall communicate, without delay, to ESAOTE any obstacle or circumstance which could, even potentially, be detrimental for the performance by the Healthcare Professional of the obligations and conditions of this Agreement.

Subject to the provision of the first paragraph of this Article, ESAOTE shall have the right to terminate the Agreement before its expiration at any time with a 30 days prior notice and ESAOTE shall also, at its sole discretion, choose to ask Dr. the Healthcare Professional to stop any activity during the termination notice period.

ESAOTE shall also have the right to terminate immediately this Agreement after 30 days of objective impossibility of the Healthcare Professional to carry out the Activities or for just case and in case of breach by the Healthcare Professional of one or more of his/her obligations under this Agreement, with the right for ESAOTE to claim the compensation of the damages.

#### Article 10 - Compensation

The compensation for the Activities carried out by the Healthcare Professional will amount to  $\in [\bullet]$ .

The abovementioned amount shall be a forfeit amount for all Activities under this Agreement for its duration and will be paid as follows:  $[\bullet]$ .

ESAOTE commits itself to pay to the Healthcare Professional the amount net of fiscal and social security deductions as applicable, by bank transfer on the bank account indicated by the Healthcare Professional. The compensation was agreed by the Parties also by derogating to any professional rate, considering the continuous relationship, the cooperation modalities as well as the professional content of the Agreement and covers any compesantion and/or economic request from the Healthcare Professional regarding the execution of the Activities under this Agreement.

ESAOTE will reimburse the Healthcare Professional for reasonable travel and out-of-pocket pre-approved expenses incurred by the Healthcare Professional while performing the Activities, within the limitations set forth in the then applicable ESAOTE policy.

In any case all expenses shall be subject to approval in advance by ESAOTE prior to being incurred and the Healthcare Professional must submit copies of appropriate receipts for any such expenses.

In case of early termination pursuant to Article 9, the Healthcare Professional will have the right the receive the compensation and reimbursement of expenses for the Activities carried out as at the date of the termination.

In case of early termination by ESAOTE for just case and/or due to a breach by the Healthcare Professional of his/her obligations of this Agreement, ESAOTE will have the right to claim the compensation of any damages suffered or to be suffered.

#### Article 11 - Compliance with law and policies

The Healthcare Professional shall perform the Agreement and shall conduct all the Activities in compliance with applicable laws, regulations and professional codes of conduct (including the Assobiomedica code of conduct and COCIR principles).

The Healthcare Professional acknowledges and confirms that: **(A)** the Loan for Use of the Equipment and the compensation contemplated by this Agreement do not improperly reward, induce and/or encourage the Healthcare Professional to purchase, lease, recommend, use, supply or procure any ESAOTE's product or service, and **(B)** he/she has not exercised during the last three years any authoritative and/or negotial power on behalf of a public administration towards ESAOTE.

In any case, the Healthcare Professional shall conduct the Activities in a manner to avoid and, in case, to promptly disclose and resolve any Conflict of Interest which may arise in the interactions between the Parties. For the purpose of this clause "Conflict of Interest" means any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision.

If applicable, the Healthcare Professional will obtain and provide the written consent of his/her employer pursuant to Italian Legislative Decree. 165/2001 at least [one week] in advance of commencing the Activities. The Consultant acknowledges that it will not be entitled to perform the Activities and to receive compensation without obtaining the necessary employer consent, where required under applicable laws.

The Healthcare Professional acknowledges that ESAOTE adopted: (i) a Code of Conduct, (ii) an Organization, Management and Control Model in compliance with Legislative Decree No. 231 of 2001 and (iii) a policy regulating the interactions with Healthcare Organizations and Healthcare Professionals whose principles are here attached under "4" (the "Policy"). The provisions of the Code of Conduct and the Organization, Management,

and Control Model can be found on the website <a href="www.esaote.com">www.esaote.com</a>, and constitute an integral and substantive part to this Agreement.

In the performance of the activities herein set out the Healthcare Professional agrees to adhere to and comply with ESAOTE's Code of Conduct, the Organization, Management, and Control Model and the Policy, insofar as they are applicable to the Healthcare Professional, and thus, by signing this Agreement, the Healthcare Professional also agrees to comply with the provisions therein contained.

The Healthcare Professional (1) has not been convicted of any offence involving bribery, corruption, fraud or dishonesty or involved in any other ethical violations or professional misconduct or negligence, (2) is not, so far as the Healthcare Professional is aware, the subject of any investigation, inquiry, enforcement proceedings or legal action by any governmental, administrative, regulatory, industry, professional body or third party regarding such kind of offences, and (3) shall promptly inform in writing ESAOTE should any of such investigation, inquiry, enforcement proceedings or legal action be notified to him/her.

In case of violation by the Healthcare Professional of any obligation set forth under this clause, ESAOTE shall be entitled, pursuant to Article 1456 of the Italian Civil Code, to terminate this Agreement for all purposes of law, and to bring action against the Healthcare Professional to claim compensation of the relative damages.

### Article 12 - Hygiene and Safety in the Workplace - Mutual Disclosure on Specific Risks and Management of Risks from Interferences

 ESAOTE guarantees full compliance with the obligations provided under Legislative Decree 81/08, as amended, for the purpose of protection of the health and safety of its workers in the workplace.

Should ESAOTE's staff, in line with the times and as provided in this Agreement, occasionally visit in work environments under the legal control of the Healthcare Professional, including in areas featuring risks other than those specifically assessed by ESAOTE, the latter undertakes to provide to the Healthcare Professional all the necessary and sufficient information on the risks connected with ESAOTE's activities, for the purpose of enabling the Healthcare Professional to analyze possible interferences between works. ESAOTE agrees to provide its full collaboration necessary to such end.

2. In the performance of the activities herein agreed, the Healthcare Professional] agrees to keep ESAOTE informed of the risks present in the areas where ESAOTE's members of staff may operate, promoting a full cooperation and coordination activity, and the drafting of a Single Document for the Assessment of Interference Risks (*Documento Unico di Valutazione dei Rischi da Interferenza, or DUVRI*) pursuant to Article 26 of Legislative Decree 81/08, as amended, which is to be deemed an integral and substantive part to this Agreement.

#### Article 13 - Personal Data Processing

By executing this Agreement, the HCP, acknowledges to be Data Owner of the data collected, registered, organized and saved in the memory of the Equipment.

In the event that ESAOTE, during the performance of this Agreement carries out any activity relating to the processing of data pursuant to art. 4, par. 2) of the European Regulation 679/2016 - GDPR, the HCP undertakes to promptly appoint ESAOTE as External Processor pursuant to art. 28 of the above mentioned European Regulation, under the following conditions:

#### Data processor shall:

- a) process Personal Data in accordance with and for the specific purposes of the performance of Technical Service Activities and pursuant to the Information Notice attached to the General Terms and Conditions
- b) maintain the highest level of confidentiality about the Personal Data;
- ensure that people authorized to the processing of Personal Data under the authority of the Data Processor is bounded to the duty of confidentiality;
- train people authorized to process Personal Data under the authority of the Data Processor and provide them with adequate instructions relating to data processing activities, monitoring the compliance;
- e) ensure that adequate technical and organizational measures are implemented to ensure a level of security appropriate to the risk, in accordance with Art. 32 of GDPR;
- f) assist the Data Controller, to the extent applicable, in the execution of the Data Protection Impact Assessment and prior consultation, in accordance with Art. 35 and 36 of the Regulation;
- appoint System Administrators and monitor their activity in compliance with the Provision issued by the Data Protection Authority on November 27, 2008 (and subsequent amendments and additions);
- h) promptly both communicate to the Data Controller criticalities and flaws concerning data protection and indicate whether any instructions received by the Data Controller, in its opinion, violates the GDPR or other provisions relating to data protection;

- i) inform the Data Controller about investigations carried out by the Data Protection Authority or any other Authority that involve Personal Data;
- j) notify the Data Controller any Personal Data breach likely to result in a risk to the rights and freedoms of the data subjects, according to the manner and providing all the information pursuant to art. 33 of the GDPR and supporting the Data Controller for the consequent communications to the data subjects referred to in art. 34 of the GDPR;
- k) keep a written record of the processing activities carried out on behalf of the Data Controller pursuant to art. 30 of the Regulation provide to the Data Controller a report showing the status of the activities carried and the measures put in place to comply with GDPR pursuant to art. 30 of the GDPR;
- when the Data Processor needs to transfer Personal Data to a third country or an international organization in compliance with Union or Member State law, it informs the Data Controller of this legal requirement before processing, unless that law prohibits such information on important grounds of public interest;
- m) for the purposes of processing Personal Data for the purposes under letter a) above, in the case where the Data processor intends to make use of Sub-Processors or in the case where any information provided to the Data Controller is to be updated or amended, the Data Processor shall previously inform the Data Controller including the identity, contact details and the relevant activities carried out by the Sub-processors. In case the Data Controller does not make opposition within 5 days from the notification by the data processor, the use of the sub-contractor and appointment of sub-processor shall be authorized.
  - In case of the appointment of Sub-Processor, the Data Processor shall impose on the same the obligations set out in these Conditions. If, furthermore, the Sub-Processor fails to comply with its data protection obligations, the Data Processor retains the entire responsibility for the fulfillment of the obligations of the other party towards the Data Controller.
- delete or return all the personal data after the end of the provision of services relating to the processing and delete existing copies, unless Union or Member State law requires storage of the personal data;
- o) make available to the Data Controller all the information necessary to demonstrate compliance with the obligations referred to in this appointment letter and allow and contribute to the review activities, including inspections, carried out by the data controller or another person appointed by them.

ESAOTE will process the HCP personal data as per the Information Notice here attached under "5".

In addition to the above, at the termination of this Agreement, the HCP undertakes to return the Equipment without any data ownership of which is of the HCP.

It remains understood that ESAOTE will have the right to receive data anonymized according to ESAOTE Procedure here attached under "6" regarding data subjects collected and/or anyhow processed ny means of the System.

ESAOTE will be therefore authorized to freely use anonymized data received and/or obtained as described above in order to improve ESAOTE products and/or services and/or to develop new products and/or services with no obligation to grant anything to the HCP for any reason whatsoever.

To this effect, the HCP declares and acknowledges that ESAOTE anonymization process is legitimate as well as the subsequent use of anonymized data for the abovementioned purposes.

The HCP also declares and guarantees to have all necessary authorizations and consents for for processing personal data to the effect of this Contract.

The HCP undertakes to release ESAOTE from any consequence, loss of action, even carried out by third parties, deriving from the violation by the HCP of the declarations and warranties here described.

#### Article 14 - Governing Law and Jurisdiction

This Agreement is governed under the laws of the Republic of Italy.

Any dispute arising out of or in connection to the interpretation or performance of this Agreement shall be subject to the exclusive jurisdiction of the Court of Genoa, Italy.

Read, confirmed, and signed				
	/	_/		
Dr. [•]				
For ESAOTE				

Description of the equipment object to this Agreement as per point 5.

Code	Description
[•]	[•]
	Add Probes or Other

## Description of the Activities

#### Teaching/Training:

Description of the Activity: <fill in according to the activity> Course of Action: <fill in according to the activity> Expected Results: <fill in according to the activity>

#### Collection of Environmental Video and Pictures

Course of Action: <fill in according to the activity> Expected Results: <fill in according to the activity>

#### Collection of Clinical Images and Clips:

Expected Results: <fill in according to the activity>
The Healthcare Professional agrees to provide to ESAOTE the data and images collected, in anonymous form and in any case in the respect of the patients' privacy.

#### Development of Promotional Material, including White Papers and Interviews:

Expected Results: <fill in according to the activity>

#### Tests (post CE marking) connected with the IQ Software release:

Description of the Activity: <fill in according to the activity>
Course of Action: <fill in according to the activity>
Expected Results: <fill in according to the activity>

#### COMPANY TRADEMARK AND TRADEMARK USE REGULATION

#### TRADEMARK



## SECTION 1. - LEGAL OWNERSHIP AND DESIGNATION OF THE TRADEMARK

Esaote is the legal owner of the trademark described in section No. 2 of these rules. Individuals who are granted authorization to make occasional and temporary use of the Trademark expressly recognize that Esaote is the sole legal owner of the Trademark; moreover, they recognize the value and goodwill associated with the trademarks and acknowledge that value and goodwill belong exclusively to Esaote. They further recognize that the right to use the Trademark must be exercised in strict obedience to the conditions and Terms of these rules, and that they will not at any time or in any way acquire any further rights to the trademark, under its use in the forms authorized by Esaote.

#### SECTION 2. - DESCRIPTION OF THE TRADEMARK

The trademark



corresponds to the characteristics described in document No. MAK000115 Ver. 01 "Corporate Identity - The new guidelines for the use of the Esaote Trademark and its applications".

#### SECTION 3. - PURPOSES AND AIMS OF THE TRADEMARK

By means of the Trademark, Esaote intends to pursue the following goals:

- to promote the corporate image;
- to identify technologies, activities, and services generated by the Company;
- to enhance less invasive, more accessible methods of diagnostic imaging, offering, at the same time, higher efficiency standards, such as those developed by Esaote;
- to spread the values of creativity, innovation, and excellence in research and development that are particular to the Company's story.

For these key reasons, the trademark must be protected and safeguarded.

#### SECTION 4. OWNERSHIP OF THE TRADEMARK

The Trademark is owned exclusively by Esaote SpA.

Only Esaote has the right to authorize the use of the Trademark by third parties who so request it, specifying the terms, methods and limits of that use.

#### SECTION 5. USE OF THE TRADEMARK

Individuals who are granted authorization to make temporary and occasional use of the Trademark undertake:

- to not use the Trademark in any way, not even through a third person, if it is not included in the ways provided by these Rules, by the manual "Guidelines for the use of the Esaote Trademark" or, anyhow, by the forms specifically established at the moment of authorization;
- to not use in any way, even through a third person, distinguishing images, other images, words, or names that are similar to and/or may be confused with the Trademark;
- to not register trademarks or domain names in their own name that incorporate the words, letters, writing, images or colors that characterize the Trademark, nor any trademark that could be confused with that of Esaote or that is based on it or that could be considered derived from it in any way;
- to not make any sort of variation, addition, or graphic, chromatic or literal modification to the trademark, that is, to not use the trademark in connection, combination, or together with other trademarks, names, words, images, symbols, or colors without prior written approval from Esaote;
- to not depict, display, or promote together with the depiction of the Trademark, trademarks referring to or products made by Esaote's competitors;
- to not sub-grant, transfer, or authorize use of the Trademark to third parties, as that use must only be made directly by the individuals authorized by Esaote;
- to not grant to third parties in sub-license or to any other titles the right or power to use the Trademark, even only partially, as granted by Esaote.

Esaote reserves the right to demand suspension of all forms of the Trademark's use at any time, when that use is not made in compliance with the conditions here defined.

Consequently, the user cannot make partial use of the Trademark nor modify it in any way, but must use it in its entirety, and in the shapes, dimensions, graphic depiction, and colors as provided by the manual "Guidelines for the use of the Esaote Trademark", or in any case, in the forms specifically established at the moment of authorization. The Guidelines' duration is unlimited.

#### SECTION 6. DURATION OF THE AUTHORIZATION

The duration of the right to use the Trademark will be determined at the time of authorization, with expiration of all rights of use occuring for that defined period without the necessity of any formal correspondence, except in cases of suspension, revocation, forfeiture, or cancellation, in accordance with the methods described in sections 9, 10, and 11 of these rules.

#### SECTION 7. TRADEMARK PROTECTION

Use of the trademark for activities in contrast with Esaote's constitutional aims is strictly prohibited.

The user recognizes the trademark's prestige and, consequently, undertakes to use the trademark with the utmost care and diligence. As such, all activities carried out by the user while using the Esaote trademark must be performed in such a way so as not to damage Esaote's image or in any way harm the trademark's reputation. In particular, the user agrees not to use the Trademark in a way that is deceptive toward the public.

The user recognizes that the trademark is the exclusive property of Esaote and agrees to immediately inform the same of any third party action or event that may constitute a real or suspected violation of the rights of Trademark ownership, reporting every objection, complaint, or warning related to the use of the Trademark, as well as any falsification that has come to his/her attention.

The user and Esaote will, therefore, lend each other reciprocal collaboration in every effort meant to protect and defend the trademark, subject to Esaote's full autonomy and discretion in the adoption of measures deemed opportune for the purposes above indicated.

Esaote may carry out inspections, directly or via third parties, to ensure the correct use of the trademark.

In accordance with that which is provided by trademark protection law, Esaote has the right to initiate legal proceedings against all those who use the trademark without prior authorization.

#### SECTION 8. NON-AUTHORIZED USE OF THE TRADEMARK

In the case of non-authorized use of the Trademark or use of the Trademark that diverges from the regulations imposed at the time of authorization, Esaote will order immediate cessation of the use, as well as the destruction of all related materials or the interruption of all activities deemed damaging to Esaote's rights, operating in the appropriate central offices for the protection of its rights.

Use of the Trademark by any individual who is not authorized or in divergence with respect to the terms of authorization will be prosecuted by Esaote in accordance with the measures provided by national and international laws for the protection of intellectual property.

#### SECTION 9. CANCELLATION AND FORFEITURE

With all other powers of cancellation according to the provisions of the law still holding, noncompliant use of the trademark with respect to the terms and methods established by these Rules, by the Guidelines for the Use of the Esaote Trademark, and by the specific regulations potentially dictated by Esaote at the time of authorization will entail Esaote's right to cancel the

contract pursuant to and in accordance with Art. 1456 of the Italian Civil Code, with the associated automatic rescindment of the authorization.

If Esaote voluntarily ends use of or modifies the Trademark, existing authorizations for the use of the Trademark expire automatically without any expenses charged to Esaote.

In all cases of suspension of the effects of authorization for the use of the Trademark, including expiration, cancellation, and forfeiture, the user is duty bound to immediately cease any activity that involves the use and depiction of the Trademark, and in any case, to cease any distribution of materials in which the Trademark is depicted (such as catalogues, leaflets, labels, websites, or any other communicative material).

#### SECTION 10. REVOCABILITY OF THE AUTHORIZATION

Authorization for the use of the trademark may be unilaterally revoked by Esaote at any time. Anyhow, the contract will be understood as cancelled by operation of law in the case of:

- a) bankruptcy or subjection to other insolvency procedures on the part of the user;
- b) behavior on the part of the user not complying with the established regulations;
- actions done by the user in the use of the trademark resulting in cases of criminal offence or infractions.

## Principles of the ESAOTE Policy on interactions with Healthcare Organizations and Healthcare Professionals

The interaction between all Group Companies and Healthcare Professionals/Healthcare Organisations is an important feature in achieving mission to make safe, innovative and reliable technology and related services available to more people. The development of innovative medical devices and technologies and the improvement of existing products require collaboration with Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services. The safe and effective use of medical technology and related services requires to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support. The support of medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction all Group Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the relationship.

For such purpose, the following **ten general principles** must always be abided in any case of interaction with Healthcare Professionals/Healthcare Organisations:

- 1. All the interactions must be transparent and comply with national and local laws, regulations or professional codes of conduct.
- 2. Interaction with Healthcare Professionals/Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of our products.

- 3. All the materials and information shared with Healthcare Professionals/Healthcare Organisations must be accurate, balanced, fair, objective, complete, not misleading and be substantiated by the appropriate evidence.
- 4. Never provide, offer or promise anything of value to improperly influence a decision affecting any of our business, including any decision regarding the purchase and supply of our products.
- Anything provided of value must be given without expectation of reciprocity, explicit or implied obligation, favour, or action in return.
- 5. Always consider and resolve any potential conflict of interest which has been identified in interactions with Healthcare Professionals/Healthcare Organisations. A conflict is any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision.
- There must always be a real, genuine and legitimate business need for our interactions with Healthcare Professionals/Healthcare Organisations.
- 7. Anything provided of value must be appropriate in the circumstances, be reasonable in value when measured by local market conditions and must be infrequent when combined with all types of benefits (for example, fees for service and hospitality) provided cumulatively. The assessment of whether the benefits are infrequent, must be made on a case by case basis. To determine frequency, we need to assess whether the additional benefit (when combined with all previous benefits provided, usually within a 12 month period) might undermine the independence, and/or improperly influence the decision making, of the recipient for the benefit of our business. Any fee for service must not exceed the fair market value of the services provided.
- 8. Anything provided of value must be given openly and transparently and must be accurately recorded in our books and records. It must be provided in a manner that would not result in adverse reputational impact or embarrassment to us if publicly disclosed.

- 9. All payments to Healthcare Professionals/Healthcare Organisations must be publicly disclosed where required under applicable law and industry standard to which we adhere.
- 10. For interactions with Healthcare Professionals/Healthcare Organisations, such as where services are performed by a Healthcare Professional for or on behalf of us, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Company.

# INFORMATION NOTICE PURSUANT TO ART. 13 OF THE REGULATION (EU) 2016/679 AND TO THE APPLICABLE LAWS AND REGULATIONS

1. Pursuant to the General Data Protection Regulation (hereinafter "GDPR") and to the applicable laws and regulations, ESAOTE S.p.A., with legal address in Genoa (Italy), Via Enrico Melen, 77, (hereinafter, "the company") as a Data Controller of the HCP personal data and in the capacity of legal representative, hereby informs the HCP regarding the processing of the HCP personal data.

#### 2. Processing purposes.

The HCP personal data and, where appropriate, the HCP relatives' personal data may be processed in relation to the activities carried out by the company for the following purposes:

- fulfilment of legal and regulatory requirements. The provision of the HCP personal information is mandatory to pursue this purpose and an explicit consent is not required.
- b) fulfilment of purposes strictly related to the management and the execution of the contract. The provision of the HCP personal information is discretionary, anyway a refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described in the contract to which the privacy notice is attached.
- c) functional to Esaote activities:
  - promotion and selling of Esaote's products or services (executed through the
    provision of commercial information related to economic, administrative and
    commercial activities of the Company via phone, mail, carriers, fax, e-mail and
    through the private area of our website.
  - performance of surveys to assess the satisfaction of the customers through interviews or questionnaires;
  - processing of studies and market researches performed by Esaote via interviews or questionnaires.

Such processing activities will not involve special categories of personal data.

#### 3. Processing legal grounds.

The processing of the HCP personal data carried out by the company, as detailed for the purposes a) and b), is necessary to execute the obligations arising from the present contract. The legal ground to perform the activities detailed at the purpose c) is the HCP explicit consent.

## 4. Processing methods.

In relation with the abovementioned purposes, data are processed either manually (processing of documents and paper documents) and/or with computer methods and procedures, only for the purposes for which they were collected and ensuring data security and confidentiality according to what defined in the policies that transpose the applicable legislation.

Data processing shall be carried out within the scope and with the arrangements envisaged by the Data Protection Authority and includes data collection, recording, retention, rectification, communication, erasure, diffusion, etc.

5. Obligatory nature of providing the requested data.

The provision of the HCP personal information is mandatory, with regards to the purpose a), and discretionary, with regards to the purposes b) and c).

A refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described at the purpose b), and thus to perform the contractual relationship.

The consent for the activities detailed at the purpose c) is mandatory.

#### 6. Data retention.

The HCP data will be processed and kept for no longer than is necessary for the purposes for which data are collected. The HCP personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes and for a time defined by law.

With regards to the purpose c), the HCP data will be maintained in a specific database no longer than 10 years.

#### 7. Communication and disclosure of personal data

The HCP personal data may be communicated to Public Authorities, pursuant legal obligations, and to external parties involved in the execution of the purposes detailed above, with specific detail to:

- welfare and social services;
- advisors, partners and freelances;
- companies of Esaote Group;
- banks and/or credit institutions;
- insurance institutions.

Data will not be communicated to other parties, nor will be disclosed without the HCP express consent.

#### 8. Data subjects' rights.

The Regulation identifies in art. 15-22 distinct rights that the data subject can exercise against the data controller. These rights are right of access to personal data, right to rectification, to erasure, right to restriction of processing, right to data portability, right to object, right to lodge a complaint to the Authority.

Requests should be sent to: privacy.esaote@esaote.com

#### 9. Data controller.

The Data Controller is Esaote S.p.A., with legal address via Enrico Melen 77, 16152 Genova, Italia.

Our employees and staff are authorized to process personal data in relation to their tasks, roles and responsibilities. Thus, they have the right to process the HCP personal data within the limits of their competences and pursuant to the instructions given by the data controller.

#### 10. Data Protection Officer (DPO)

The Data Protection Officer is Gabriele Faggioli and his contact references are: dpo.esaote@esaote.com.

# Anonymization of personal and special patient data

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### 1. Purpose

The aim of these instructions is to describe how to anonymise personal and special patient data, as required in particular by the document "Rules for the processing of personal data and special data during R&D activities", that gives the instructions to which the R&D personnel must scrupulously comply, in order to correctly process personal and particular patient data in accordance with the European Regulation (EU) 2016/679 of 27 April 2016 on the protection of personal data (GDPR).

# 2. Applicability

These instructions apply to the following cases:

- Exams acquired by the Esaote MRI systems.
- Exams acquired by the Esaote U/S systems.
- Exams acquired by Esaote or other systems and exported in DICOM format.

### 3. General concepts

Anonymisation, that is de-identification of the exams, is required to avoid exposing personal data and special data, as described by GDPR, to any data breach, while maintaining the capability to use them for R&D, marketing and service purposes.

The de-identification algorithms implemented in the Esaote MRI and ultrasound systems have been designed with the aim to avoid that the de-identified exams can be referred to the original patients. In any case, any anonymisation process is always subject to flaws, and some apparently irrelevant information that remains on the header of the images, or on the pixels themselves (for example, text comments) could make possible, in very particular cases, the identification of the physical person the exam belongs to. For this reason the Esaote personnel has to verify carefully that the anonymisation process is safe enough for the particular exams they are applying it.

In case for any reason the anonymisation cannot be applied, or cannot be safe enough, you need to reduce the number of exported images to the minimum necessary, use when possible an encrypted USB pen drive or an encrypted export, delete them as soon as they are not necessary anymore, and carefully scrub the USB pen drive, or destroy the CD-R used to export the original data before the anonymisation.

# 4. Anonymisation from Esaote MRI systems

# 4.1 Anonymisation when exporting

On the current systems, when you need to de-identify one or more exams when exporting them, the following procedure must be used.

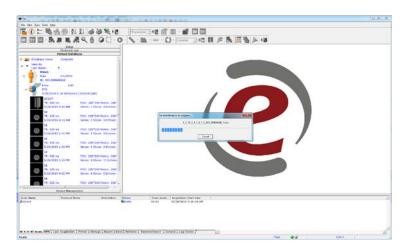
From Opi Patient Tree Tab, select the Patient, Study o Series to export de-identified. Choose from the Tools menu, "Service->Export to device..." item.



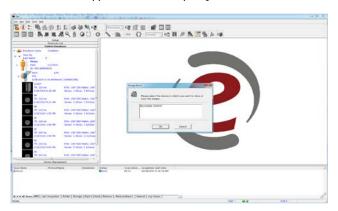
Confirm when asked, that you want to export to DICOM Media:



The de-identification process starts:



At the end, the application asks to specify the device to which de-identified images shall be copied:



# 4.2 Legacy systems

If the exams are contained in a system running a software release that does not support the above procedure, you need to export them in DICOM, and then to anonymise the exported data as described in the chapter 6. Do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

# 5. Anonymisation from Esaote ultrasound systems

The exams contained in the internal database of the Esaote ultrasound systems can be anonymised using the procedure described in the following paragraph 5.1, when possible.

Otherwise you can anonymise the exams by exporting them in Multimedia format (AVI, BMP, JPG etc.), see the following paragraph 5.2.

To get the complete de-identification of the exams exported in Native format see the following paragraph 5.3.

To get the complete de-identification of the exams exported in DICOM format see the chapter 6.

# 5.1 Local anonymisation

On some of the current systems, when you need to de-identify one exam leaving it in the local database, the following procedure can be used.

Select the exam to anonymise, open it, press Patient ID and in the panel press the "Anonymize" button. The patient data are immediately de-identified.

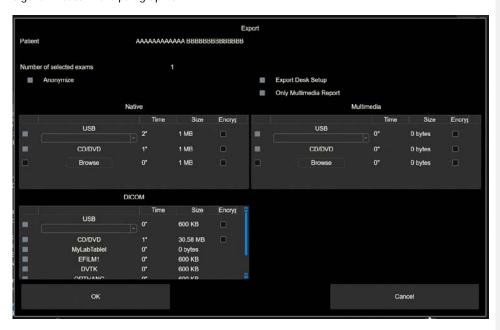


In case the above button is not available, export the exam(s) using the procedure described at paragraph 5.3 and remove them from the local database.

# 5.2 Multimedia anonymisation

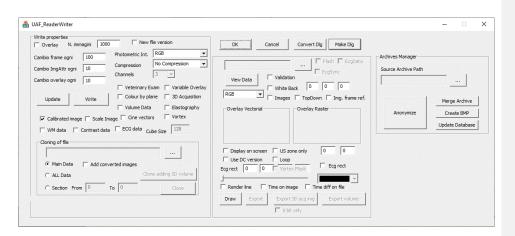
When you need to de-identify one exam exporting it in multimedia format (AVI, BMP, JPG etc.), the following procedure must be used.

Select the exams to anonymise, press Export, and from the Patient ID panel press the "Anonymize" button. The patient data are exported in the selected format(s) using the same algorithm used in the paragraph 0.



# 5.3 Native format anonymisation

The complete anonymisation of one or more exams exported in Native format can be done using the software "UAF Reader/Writer", provided by Esaote as P/N SWE000993. You need to obtain the latest release, to install it in you personal computer (running Windows 10) and to launch it. The following panel appears:



In the "Archives manager" section select, for "Source Archive Path", the folder where the exported database is stored, and press "Anonymize": the exported database will be fully anonymised, so you can import it in a compatible Esaote ultrasound system, using the Database rebuild function.

After the anonymisation, do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

# 6. Anonymisation of DICOM exams

Anonymisation of DICOM exams (exported from any Esaote system) should be performed using the tool DicomCleaner. It is a free open source tool with a user interface for importing, "cleaning" and saving sets of DICOM instances (files); it has been designed by David Clunie, one of the major DICOM experts in the world, and is produced by his company, PixelMed. The tool can be freely downloaded from

http://www.dclunie.com/pixelmed/software/webstart/DicomCleanerUsage.html

where you can also find all the needed information about its usage. The tool can also blank pixel areas that contain personal information.

After the anonymisation, do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

#### 7. Annexes

Not Applicable

### 8. Revision info

First issue

# COLLABORATION (AND LOAN FOR USE) AGREEMENT WITH HEALTHCARE PROFESSIONAL (HCP)

- This standard is attached to Esaote Group Key Opinion Leaders Guidelines;
- This standard is ruled under Italian Law;
- The responsibility of ensuring localization of this standard under local applicable laws stays within the relevant company in Esaote Group;
- The same standard applies for:
  - R&D;
- The function initiating the process is responsible for defining the exact and appropriate scope of work of the Agreement.

This page is merely explanatory and must be removed from the agreement draft.

#### COLLABORATION AND LOAN FOR USE AGREEMENT

#### **BETWEEN**

ESAOTE S.p.A., with headquarters in Via Enrico Melen, 77 - 16152, Genoa, Italy, Taxpayer Identification and VAT Code No. 05131180969, hereinafter simply referred to as **ESAOTE**, represented by its Representative [•], endowed with the necessary powers,

#### AND

[•] hereinafter simply referred to as **Healthcare Professional** ("HCP")

#### WHEREAS

- ESAOTE has for years been engaged in the development of innovative ultrasound technology with high spatial resolution, MRIs, and diagnosis support clinical software, focusing on specific pathologies.
- ESAOTE is interested in promoting its products, its activities and its image on the territory in compliance with its ethical principles, trough professional doctors who are not part of Esaote's organization and who have appropriate professional compentencies.
- 3. The Healthcare Professional, Dr. [•], specialized in [•], enrolled in the [•] register, has developed a multi-year experience in the field of diagnostics and of medium-high intensity care and considering the specific activities as well as his experience, showed his/her interest and his/her availability to start a collaboration with Esaote by defining autonomously processes, timing and sites to carry out his/her activities.
- In particular, The Healthcare Professional asked ESAOTE to enter into a loan for use of ESAOTE equipment for exclusive scientific purposes and aiming at the best health safeguard.
- 5. ESAOTE is in turn interestested in a collaboration with the Healthcare Professional making ESAOTE equipment temporarily available under the conditions specified below and taking advantage of Healthcare Professional's expertise, competencies, medical and healthcare experiences, as well as of his/her professionality, with a collaboration under art. 2229 of the Italian Civil Code and subject to Healthcare Professional's availability.
- 6. The Parties expressely agree to exclude any subordination relationship.

- 7. ESAOTE holds, and shall continue to hold for the entire duration of this Agreement, all the authorizations and licenses necessary to own full rights over the trademark (word and figurative) reproduced in Attachment 3 (hereinafter the "Trademark"), and to grant rights under this Agreement.
- 8. The Parties agreed to execute this Agreement in order to manage their collaboration. All the above mentioned:

# THE PARTIES THEREFORE AGREE AND COVENANT AS FOLLOWS Article 1 - Recitals

The Recitals are an integral and substantive part to this Agreement.

#### Article 2 - Object

ESAOTE engags the Healthcare Professional to carry out collaboration activities in the following areas, as further detailed in Attachment [•] and below ("Activities"):

- 1. Teaching/Training
- 2. Collection of environmental videos and pictures
- 3. Collection of clinical images and clips
- 4. Development of White Papers, Promotional Material, Interviews
- 5. Test (post CE marking) connected with the IQ Software release

The Activities shall be carried out subject to Healthcare Professional's availability and with the necessary coordination with ESAOTE.

In addition to the above, the Healthcare Professional shall be, subject to his/her availability, carrying out application trainings on MRI systems to ESAOTE customers on the territoty as specified below:

- Application corrective interventions at ESAOTE customers
- Commercial demos on ESAOTE MRI systems
- Presentations of ESAOTE MRI sisystems at ESAOTE study centers as, as an example, MR-Academy.

#### Article 3 - Performance of the Activities

The Activities shall be carried out as detailed in Attachment [●] herein.

The Healthcare Professional will be free to organize and manage all aspects and methodologies of the Activities with no duty of presence and/or venue and/or time, different from those relating to the

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achievement of the best result of the Activities, in complete decisional and operative freedom, except for the necessary coordination with ESAOTE.

The Healthcare Professional, under his/her own responsibility, represents and warrants to have completed all the necessary procedures and to have obtained all the necessary authorizations to sign and perform this Agreement in compliance with the applicable laws and regulations.

The Healthcare Professional, under his own responsibility, also warrants that he/dhe is allowed to carry out the Activities as described under Article 2 and in Attachment [•], pursuant to the law as well as to other applicable regulations applicable both in Italy and abroad.

The Healthcare Professional is available to attend meetings as well as training sessions and to share with ESAOTE all the activities and relevant results, that will be agreed by the Parties on the basis of their respective availability.

#### Article 4 - Activities of the Healthcare Professional

The Healthcare Professional agrees to:

- Indicate, in every type of documentation produced, that the activities have been carried out with ESAOTE equipment.
- Maintain appropriate records in relation to the provision of the Equipment by ESAOTE, including proof of receipt for any Equipment delivered by ESAOTE and proof of delivery of any Equipment returned to ESAOTE.
- 3. Provide the following reports within the timeframes indicated below:

Frequency	Report					
Semiannual report, calculated	Progress	and	Final	Report	on	the
starting on the date of validity	performance of the Activities.					
of this Agreement.						

4. Enable the members of staff of ESAOTE, as previously communicated by ESAOTE, to carry out jointly agreed visits for the purpose of assisting in the Activities and reaching the objectives detailed under Attachment [•] hereto.

#### Article 5 - Loan for Use

For the purpose of assisting in the Activities, ESAOTE makes available to the Healthcare Professional, under a free-of-charge Loan for Use, one piece of equipment, with CE marking, in compliance with the European directive on medical devices, and described in Attachment 2 herein ("Equipment"), and agrees to provide introductory training for the purpose of using the Equipment to the doctors who shall make use thereof, with the expected duration of 1 (one) week. The Equipment shall be placed within the facilities of the Healthcare Professional and shall be used with care and diligence. The Healthcare Professional shall abstain from any use of the Equipment other than those expressly granted under this Agreement and/or necessary to perform the Activities.

The Healthcare Professional shall bear any costs connected with the use of the Equipment. For the entire duration of this Agreement ESAOTE shall bear all the costs relative to an insurance policy covering against fire and theft, and to the ordinary and extraordinary maintenance of the Equipment. Consumables are expressly excluded.

The Healthcare Professional shall be held liable for any loss and/or damage to the Equipment caused by the negligence of the users, for any reason whatsoever.

The Healthcare Professional expressly indemnifies and holds ESAOTE harmless form any liability for damages to persons of things deriving from the use of the Equipment, unless said damages are caused by flaws and/or design and/or manufacturing defects. Pursuant to and by effect of Article 1806 of the Civil Code, any damage or loss of the Equipment will be charged to the Healthcare Professional, also in the event that such damage or loss is due to unforeseeable circumstances or is not attributable to the Healthcare Professional. To this effect, the Parties estimate the total value of the Equipment in [•]. Upon termination of this Agreement, ESAOTE shall remove the Equipment at its sole care and expense.

Article 6 - Confidentiality

- The Healthcare Professional guarantees to maintain, towards any person non-authorized by ESAOTE, full confidentiality as regards to any information, knowledge on the performance and the status of the Equipment, as well as to any confidential document they may become aware of within the scope of this Agreement or any future agreement and/or protocol.
- 2. The Healthcare Professional agrees to treat as confidential and not to disclose, either directly or indirectly, any information concerning ESAOTE and the products designed by the latter, of which they may gain knowledge during the performance of the Activities. Specifically, the Healthcare Professional acknowledges that such information shall be deemed property of ESAOTE, and agrees:

Commentato [OF1]: specificare

- to keep said information as confidential and disclose it exclusively to members of staff of the Healthcare Professional limited to what is strictly necessary for the purpose of performing the Activities, demanding the strictest confidentiality.
- not to copy, disassemble, or in any way interfere with the hardware and the software of ESAOTE S.p.A.'s Equipment.
- if required by ESAOTE, promptly return every piece of written information and any copy thereof.
- This confidentiality agreement does not apply to any information already in the public domain or which was available to the Healthcare Professional at a time prior to the signing of this Agreement.
- 4. This confidentiality agreement is binding for the duration of this Agreement and for a period of five (5) years after the termination thereof.

#### Article 7 - Obligation of the Healthcare Professional and use of the trademark

- ESAOTE grants to the Healthcare Professional the right to use the Trademark, exclusively
  in the measure in which the use of the Trademark is necessary to the Healthcare
  Professional to carry out the Activities, for the duration and under the condition laid out
  in this Agreement.
- 2. The Healthcare Professional shall be entitled to no right to use the Trademark other than those expressly granted herein. In particular, the Healthcare Professional shall not have the right to transfer and/or grant in any way to any third party the right to use the Trademark, and undertakes to abstain from any conduct and/or from promoting any initiative connected to the Trademark, and, in any case, to the image of ESAOTE, other than those expressly provided under this Agreement, or which may damage in any way the Trademark or the image of ESAOTE.
- The Parties acknowledge and agree that, at any time during the duration of this Agreement, ESAOTE may request the Healthcare Professional, via written communication, to cease to use the Trademark, or to use a modified or different mark

(the "Modified Trademark"), which shall be communicated by the Healthcare Professional in the same manner.

The Healthcare Professional shall cease to use the Trademark upon receipt of ESAOTE's request, and shall refrain from using the Trademark until receipt of a written communication from ESAOTE requesting otherwise. Should ESAOTE request the Healthcare Professional to use the Modified Trademark, the Healthcare Professional shall use the Modified Trademark as soon as reasonably possible, and, in any case, no later than a month after receipt of the notification from ESAOTE. In this case, the costs and expenses required to promptly use the Modified Trademark shall be borne by ESAOTE, by reimbursing the Healthcare Professional promptly upon receipt of a suitable written evidence of said costs and expenses and a relative invoice.

#### Article 8 - Persons in Charge of the Collaboration

Person in charge of the Activities for ESAOTE: the project head appointed by ESAOTE to interact with the Healthcare Professional shall be [•] or any other person delegated by [•], who shall liaise for anything relating to the performance of the collaboration and of this Agreement.

Communications between the Parties shall be via e-mail of registered mail with proof of receipt:

- if to the Company: [●]
- if to the Healthcare Professional: [●]

or to a different address that the Parties can communicate each other after the date of execution of this Agreement and being agreed that the Parties choose as their domicile for any purposes of this Agreement the addresses indicated above or successively communicated.

#### Article 9 - Duration

This Agreement shall be valid from [●] until [●]. Tacit renewal is expressly excluded.

The Healthcare Professional shall communicate, without delay, to ESAOTE any obstacle or circumstance which could, even potentially, be detrimental for the performance by the Healthcare Professional of the obligations and conditions of this Agreement.

Subject to the provision of the first paragraph of this Article, ESAOTE shall have the right to terminate the Agreement before its expiration at any time with a 30 days prior notice and

ESAOTE shall also, at its sole discretion, choose to ask Dr. the Healthcare Professional to stop any activity during the termination notice period.

ESAOTE shall also have the right to terminate immediately this Agreement after 30 days of objective impossibility of the Healthcare Professional to carry out the Activities or for just case and in case of breach by the Healthcare Professional of one or more of his/her obligations under this Agreement, with the right for ESAOTE to claim the compensation of the damages.

#### Article 10 - Compensation

The compensation for the Activities carried out by the Healthcare Professional will amount to  $\in [\bullet]$ .

The above mentioned amount shall be a forfeit amount for all Activities under this Agreement for its duration and will be paid as follows:  $[\bullet]$ .

ESAOTE commits itself to pay to the Healthcare Professional the amount net of fiscal and social security deductions as applicable, by bank transfer on the bank account indicated by the Healthcare Professional. The compensation was agreed by the Parties also by derogating to any professional rate, considering the continuous relationship, the cooperation modalities as well as the professional content of the Agreement and covers any compessantion and/or economic request from the Healthcare Professional regarding the execution of the Activities under this Agreement.

ESAOTE will reimburse the Healthcare Professional for reasonable travel and out-of-pocket pre-approved expenses incurred by the Healthcare Professional while performing the Activities, within the limitations set forth in the then applicable ESAOTE policy.

In any case all expenses shall be subject to approval in advance by ESAOTE prior to being incurred and the Healthcare Professional must submit copies of appropriate receipts for any such expenses.

In case of early termination pursuant to Article 9, the Healthcare Professional will have the right the receive the compensation and reimbursement of expenses for the Activities carried out as at the date of the termination.

In case of early termination by ESAOTE for just case and/or due to a breach by the Healthcare Professional of his/her obligations of this Agreement, ESAOTE will have the right to claim the compensation of any damages suffered or to be suffered.

#### Article 11 - Compliance with law and policies

The Healthcare Professional shall perform the Agreement and shall conduct all the Activities in compliance with applicable laws, regulations and professional codes of conduct (including the Assobiomedica code of conduct and COCIR principles).

The Healthcare Professional acknowledges and confirms that: **(A)** the Loan for Use of the Equipment and the compensation contemplated by this Agreement do not improperly reward, induce and/or encourage the Healthcare Professional to purchase, lease, recommend, use, supply or procure any ESAOTE's product or service, and **(B)** he/she has not exercised during the last three years any authoritative and/or negotial power on behalf of a public administration towards ESAOTE.

In any case, the Healthcare Professional shall conduct the Activities in a manner to avoid and, in case, to promptly disclose and resolve any Conflict of Interest which may arise in the interactions between the Parties. For the purpose of this clause "Conflict of Interest" means any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision.

If applicable, the Healthcare Professional will obtain and provide the written consent of his/her employer pursuant to Italian Legislative Decree. 165/2001 at least [one week] in advance of commencing the Activities. The Consultant acknowledges that it will not be entitled to perform the Activities and to receive compensation without obtaining the necessary employer consent, where required under applicable laws.

The Healthcare Professional acknowledges that ESAOTE adopted: (i) a Code of Conduct, (ii) an Organization, Management and Control Model in compliance with Legislative Decree No. 231 of 2001 and (iii) a policy regulating the interactions with Healthcare Organizations and Healthcare Professionals whose principles are here attached under "4" (the "Policy"). The provisions of the Code of Conduct and the Organization, Management, and Control Model can be found on the website <a href="www.esaote.com">www.esaote.com</a>, and constitute an integral and substantive part to this Agreement.

In the performance of the activities herein set out the Healthcare Professional agrees to adhere to and comply with ESAOTE's Code of Conduct, the Organization, Management, and Control Model and the Policy, insofar as they are applicable to the Healthcare Professional, and thus, by signing this Agreement, the Healthcare Professional also agrees to comply with the provisions therein contained.

The Healthcare Professional (1) has not been convicted of any offence involving bribery, corruption, fraud or dishonesty or involved in any other ethical violations or professional misconduct or negligence, (2) is not, so far as the Healthcare Professional is aware, the subject of any investigation, inquiry, enforcement proceedings or legal action by any governmental, administrative, regulatory, industry, professional body or third party regarding such kind of offences, and (3) shall promptly inform in writing ESAOTE should any of such investigation, inquiry, enforcement proceedings or legal action be notified to him/her.

In case of violation by the Healthcare Professional of any obligation set forth under this clause, ESAOTE shall be entitled, pursuant to Article 1456 of the Italian Civil Code, to terminate this Agreement for all purposes of law, and to bring action against the Healthcare Professional to claim compensation of the relative damages.

# Article 12 - Hygiene and Safety in the Workplace - Mutual Disclosure on Specific Risks and Management of Risks from Interferences

- ESAOTE guarantees full compliance with the obligations provided under Legislative Decree 81/08, as amended, for the purpose of protection of the health and safety of its workers in the work place.
  - Should ESAOTE's staff, in line with the times and as provided in this Agreement, occasionally visit in work environments under the legal control of the Healthcare Professional, including in areas featuring risks other than those specifically assessed by ESAOTE, the latter undertakes to provide to the Healthcare Professional all the necessary and sufficient information on the risks connected with ESAOTE's activities, for the purpose of enabling the Healthcare Professional to analyze possible interferences between works. ESAOTE agrees to provide its full collaboration necessary to such end.
- 2. In the performance of the activities herein agreed, the Healthcare Professional] agrees to keep ESAOTE informed of the risks present in the areas where ESAOTE's members of staff may operate, promoting a full cooperation and coordination activity, and the drafting of a Single Document for the Assessment of Interference Risks (Documento Unico di Valutazione dei Rischi da Interferenza, or DUVRI) pursuant to Article 26 of Legislative Decree 81/08, as amended, which is to be deemed an integral and substantive part to this Agreement.

Article 13 - Personal Data Processing

By executing this Agreement the HCP, acknowledges to be Data Owner of the data collected, registered, organized and saved in the memory of the Equipment.

In the event that ESAOTE, during the performance of this Agreement carries out any activity relating to the processing of data pursuant to art. 4, par. 2) of the European Regulation 679/2016 - GDPR, the HCP undertakes to promptly appoint ESAOTE as External Processor pursuant to art. 28 of the above mentioned European Regulation, under the following conditions:

#### Data processor shall:

- a) process Personal Data in accordance with and for the specific purposes of the performance of Technical Service Activities and pursuant to the Information Notice attached to the General Terms and Conditions
- b) maintain the highest level of confidentiality about the Personal Data;
- ensure that people authorized to the processing of Personal Data under the authority of the Data Processor is bounded to the duty of confidentiality;
- train people authorized to process Personal Data under the authority of the Data Processor and provide them with adequate instructions relating to data processing activities, monitoring the compliance;
- e) ensure that adequate technical and organizational measures are implemented to ensure a level of security appropriate to the risk, in accordance with Art. 32 of GDPR;
- f) assist the Data Controller, to the extent applicable, in the execution of the Data Protection Impact Assessment and prior consultation, in accordance with Art. 35 and 36 of the Regulation;
- appoint System Administrators and monitor their activity in compliance with the Provision issued by the Data Protection Authority on November 27, 2008 (and subsequent amendments and additions);
- h) promptly both communicate to the Data Controller criticalities and flaws concerning data protection and indicate whether any instructions received by the Data Controller, in its opinion, violates the GDPR or other provisions relating to data protection;
- i) inform the Data Controller about investigations carried out by the Data Protection Authority or any other Authority that involve Personal Data;
- notify the Data Controller any Personal Data breach likely to result in a risk to the rights and freedoms of the data subjects, according to the manner and providing all the information pursuant to art. 33 of the GDPR and supporting the Data Controller for the consequent communications to the data subjects referred to in art. 34 of the GDPR;
- k) keep a written record of the processing activities carried out on behalf of the Data Controller pursuant to art. 30 of the Regulation provide to the Data Controller a report showing the status of the activities carried and the measures put in place to comply with GDPR pursuant to art. 30 of the GDPR;
- when the Data Processor needs to transfer Personal Data to a third country or an international organization in compliance with Union or Member State law, it informs the Data Controller of this legal requirement before processing, unless that law prohibits such information on important grounds of public interest;

- m) for the purposes of processing Personal Data for the purposes under letter a) above, in the case where the Data processor intends to make use of Sub-Processors or in the case where any information provided to the Data Controller is to be updated or amended, the Data Processor shall previously inform the Data Controller including the identity, contact details and the relevant activities carried out by the Sub-processors. In case the Data Controller does not make opposition within 5 days from the notification by the data processor, the use of the sub-contractor and appointment of sub-processor shall be authorized.
  - In case of the appointment of Sub-Processor, the Data Processor shall impose on the same the obligations set out in these Conditions. If, furthermore, the Sub-Processor fails to comply with its data protection obligations, the Data Processor retains the entire responsibility for the fulfillment of the obligations of the other party towards the Data Controller.
- delete or return all the personal data after the end of the provision of services relating to the processing and delete existing copies, unless Union or Member State law requires storage of the personal data;
- o) make available to the Data Controller all the information necessary to demonstrate compliance with the obligations referred to in this appointment letter and allow and contribute to the review activities, including inspections, carried out by the data controller or another person appointed by them.

ESAOTE will process the HCP personal data as per the Information Notice here attached under "5".

In addition to the above, at the termination of this Agreement, the HCP undertakes to return the Equipment without any data ownership of which is of the HCP.

It remains understood that ESAOTE will have the right to receive data anonymized according to ESAOTE Procedure here attached under "6" regarding data subjects collected and/or anyhow processed ny means of the System.

ESAOTE will be therefore authorized to freely use anonymized data received and/or obtained as described above in order to improve ESAOTE products and/or services and/or to develop new products and/or services with no obligation to grant anything to the HCP for any reason whatsoever.

To this effect, the HCP declares and acknowledges that ESAOTE anonymization process is legitimate as well as the subsequent use of anonymized data for the abovementioned purposes.

The HCP also declares and guarantees to have all necessary authorizations and consents for for processing personal data to the effect of this Contract.

The HCP undertakes to release ESAOTE from any consequence, loss of action, even carried out by third parties, deriving from the violation by the HCP of the declarations and warranties here described.

#### Article 14 - Intellectual Property Rights

For the purpose of this clause:

"New IPR" shall mean all IPR that may be developed during the term of this Agreement, directly or indirectly, in the performance of, or in connection with, the performance of this Agreement, whether based on ESAOTE Background IPR, whether based on HCP Background IPR, or whether jointly developed or developed independently by either party. "Intellectual Property Rights" or "IPR" shall mean all legal protection throughout the world recognized by law (whether by statute, common law or otherwise) with respect to intellectual property, including:

- all trademarks (registered and unregistered), applications, registrations, and renewals in connection therewith, service marks, trade dress, logos, trade names, Internet domain names, fictional business names and corporate names, together with all translations, adaptations, derivations, and combinations thereof and including all goodwill associated therewith (collectively, "Marks");
- 2) all industrial designs, inventions and discoveries (whether patentable or unpatentable and whether or not reduced to practice), all improvements thereto, and all patents, patent applications, statutory invention registrations, provisional patent applications and patent disclosures, together with all reissuances, continuations, continuations-inpart, divisionals, revisions, extensions, and reexaminations thereof (collectively, "Patents");
- all copyrightable works, all copyrights in both published works and unpublished works, and all applications, registrations, and renewals in connection therewith (collectively, "Copyrights");
- all rights in mask works and all applications, registrations, and renewals in connection therewith (collectively, "<u>Rights in Mask Works</u>") and
- 5) all know-how, trade secrets and confidential information (including ideas, research and development, formulas, compositions, manufacturing and production processes and techniques, technical information, data, process technology, plans, designs, drawings, specifications, blue prints, customer and supplier lists, pricing and cost information, and

business and marketing plans and proposals), all Software (including data and related documentation), all other proprietary rights, and all copies and tangible embodiments thereof, in whatever form or medium (collectively, "Trade Secrets").

"<u>HCP Background IPR</u>" shall mean an Intellectual Property Rights developed by, under control, of, or otherwise owned by HCP before the effective date of this Agreement.

"ESAOTE Background IPR" shall mean an Intellectual Property Rights developed by, under control, of, or otherwise owned by ESAOTE before the effective date of this Agreement.

ESAOTE retains complete ownership of all Intellectual Property Rights in and to the ESAOTE Background IPR.

ESAOTE shall have sole ownership of any and all New IPR.

HCP agrees to and does hereby assign all right, title and interest in and to all New IPR to ESAOTE.

HCP shall not have the right to make, have made, reproduce, make derivative works from, use, license, lease, sell, market, display, disclose, perform, distribute, import or export products embodying, utilizing or produced through the use of any New IPR or otherwise license to third parties any New IPR, without the prior written consent of ESAOTE.

#### Article 15 - Governing Law and Jurisdiction

This Agreement is governed under the laws of the Republic of Italy.

Any dispute arising out of or in connection to the interpretation or performance of this Agreement shall be subject to the exclusive jurisdiction of the Court of Genoa, Italy.

Kead, confirme	,//	
Dr. [•]		
For ESAOTE		

Description of the equipment object to this Agreement as per point 5.

Code	Description
[•]	[•]
	Add Probes or Other

## Description of the Activities

#### Teaching/Training:

Description of the Activity: <fill in according to the activity> Course of Action: <fill in according to the activity> Expected Results: <fill in according to the activity>

#### Collection of Environmental Video and Pictures

Course of Action: <fill in according to the activity> Expected Results: <fill in according to the activity>

#### Collection of Clinical Images and Clips:

Expected Results: <fill in according to the activity>
The Healthcare Professional agrees to provide to ESAOTE the data and images collected, in anonymous form and in any case in the respect of the patients' privacy.

#### Development of Promotional Material, including White Papers and Interviews:

Expected Results: <fill in according to the activity>

#### Tests (post CE marking) connected with the IQ Software release:

Description of the Activity: <fill in according to the activity>
Course of Action: <fill in according to the activity>
Expected Results: <fill in according to the activity>

#### COMPANY TRADEMARK AND TRADEMARK USE REGULATION

#### TRADEMARK



# SECTION 1. - LEGAL OWNERSHIP AND DESIGNATION OF THE TRADEMARK

Esaote is the legal owner of the trademark described in section No. 2 of these rules. Individuals who are granted authorization to make occasional and temporary use of the Trademark expressly recognize that Esaote is the sole legal owner of the Trademark; moreover, they recognize the value and goodwill associated with the trademarks and acknowledge that value and goodwill belong exclusively to Esaote. They further recognize that the right to use the Trademark must be exercised in strict obedience to the conditions and Terms of these rules, and that they will not at any time or in any way acquire any further rights to the trademark, under its use in the forms authorized by Esaote.

#### SECTION 2. - DESCRIPTION OF THE TRADEMARK

The trademark



corresponds to the characteristics described in document No. MAK000115 Ver. 01 "Corporate Identity - The new guidelines for the use of the Esaote Trademark and its applications".

#### SECTION 3. - PURPOSES AND AIMS OF THE TRADEMARK

By means of the Trademark, Esaote intends to pursue the following goals:

- to promote the corporate image;
- to identify technologies, activities, and services generated by the Company;
- to enhance less invasive, more accessible methods of diagnostic imaging, offering, at the same time, higher efficiency standards, such as those developed by Esaote;
- to spread the values of creativity, innovation, and excellence in research and development that are particular to the Company's story.

For these key reasons, the trademark must be protected and safeguarded.

#### SECTION 4. OWNERSHIP OF THE TRADEMARK

The Trademark is owned exclusively by Esaote SpA.

Only Esaote has the right to authorize the use of the Trademark by third parties who so request it, specifying the terms, methods and limits of that use.

#### SECTION 5. USE OF THE TRADEMARK

Individuals who are granted authorization to make temporary and occasional use of the Trademark undertake:

- to not use the Trademark in any way, not even through a third person, if it is not included in the ways provided by these Rules, by the manual "Guidelines for the use of the Esaote Trademark" or, anyhow, by the forms specifically established at the moment of authorization;
- to not use in any way, even through a third person, distinguishing images, other images, words, or names that are similar to and/or may be confused with the Trademark;
- to not register trademarks or domain names in their own name that incorporate the words, letters, writing, images or colors that characterize the Trademark, nor any trademark that could be confused with that of Esaote or that is based on it or that could be considered derived from it in any way;
- to not make any sort of variation, addition, or graphic, chromatic or literal modification to the trademark, that is, to not use the trademark in connection, combination, or together with other trademarks, names, words, images, symbols, or colors without prior written approval from Esaote;
- to not depict, display, or promote together with the depiction of the Trademark, trademarks referring to or products made by Esaote's competitors;
- to not sub-grant, transfer, or authorize use of the Trademark to third parties, as that use must only be made directly by the individuals authorized by Esaote;
- to not grant to third parties in sub-license or to any other titles the right or power to use the Trademark, even only partially, as granted by Esaote.

Esaote reserves the right to demand suspension of all forms of the Trademark's use at any time, when that use is not made in compliance with the conditions here defined.

Consequently, the user cannot make partial use of the Trademark nor modify it in any way, but must use it in its entirety, and in the shapes, dimensions, graphic depiction, and colors as provided by the manual "Guidelines for the use of the Esaote Trademark", or in any case, in the forms specifically established at the moment of authorization. The Guidelines' duration is unlimited.

#### SECTION 6. DURATION OF THE AUTHORIZATION

The duration of the right to use the Trademark will be determined at the time of authorization, with expiration of all rights of use occuring for that defined period without the necessity of any formal correspondence, except in cases of suspension, revocation, forfeiture, or cancellation, in accordance with the methods described in sections 9, 10, and 11 of these rules.

#### SECTION 7. TRADEMARK PROTECTION

Use of the trademark for activities in contrast with Esaote's constitutional aims is strictly prohibited.

The user recognizes the trademark's prestige and, consequently, undertakes to use the trademark with the utmost care and diligence. As such, all activities carried out by the user while using the Esaote trademark must be performed in such a way so as not to damage Esaote's image or in any way harm the trademark's reputation. In particular, the user agrees not to use the Trademark in a way that is deceptive toward the public.

The user recognizes that the trademark is the exclusive property of Esaote and agrees to immediately inform the same of any third party action or event that may constitute a real or suspected violation of the rights of Trademark ownership, reporting every objection, complaint, or warning related to the use of the Trademark, as well as any falsification that has come to his/her attention.

The user and Esaote will, therefore, lend each other reciprocal collaboration in every effort meant to protect and defend the trademark, subject to Esaote's full autonomy and discretion in the adoption of measures deemed opportune for the purposes above indicated.

Esaote may carry out inspections, directly or via third parties, to ensure the correct use of the trademark.

In accordance with that which is provided by trademark protection law, Esaote has the right to initiate legal proceedings against all those who use the trademark without prior authorization.

#### SECTION 8. NON-AUTHORIZED USE OF THE TRADEMARK

In the case of non-authorized use of the Trademark or use of the Trademark that diverges from the regulations imposed at the time of authorization, Esaote will order immediate cessation of the use, as well as the destruction of all related materials or the interruption of all activities deemed damaging to Esaote's rights, operating in the appropriate central offices for the protection of its rights.

Use of the Trademark by any individual who is not authorized or in divergence with respect to the terms of authorization will be prosecuted by Esaote in accordance with the measures provided by national and international laws for the protection of intellectual property.

#### SECTION 9. CANCELLATION AND FORFEITURE

With all other powers of cancellation according to the provisions of the law still holding, noncompliant use of the trademark with respect to the terms and methods established by these Rules, by the Guidelines for the Use of the Esaote Trademark, and by the specific regulations potentially dictated by Esaote at the time of authorization will entail Esaote's right to cancel the

contract pursuant to and in accordance with Art. 1456 of the Italian Civil Code, with the associated automatic rescindment of the authorization.

If Esaote voluntarily ends use of or modifies the Trademark, existing authorizations for the use of the Trademark expire automatically without any expenses charged to Esaote.

In all cases of suspension of the effects of authorization for the use of the Trademark, including expiration, cancellation, and forfeiture, the user is duty bound to immediately cease any activity that involves the use and depiction of the Trademark, and in any case, to cease any distribution of materials in which the Trademark is depicted (such as catalogues, leaflets, labels, websites, or any other communicative material).

#### SECTION 10. REVOCABILITY OF THE AUTHORIZATION

Authorization for the use of the trademark may be unilaterally revoked by Esaote at any time. Anyhow, the contract will be understood as cancelled by operation of law in the case of:

- a) bankruptcy or subjection to other insolvency procedures on the part of the user;
- b) behavior on the part of the user not complying with the established regulations;
- actions done by the user in the use of the trademark resulting in cases of criminal offence or infractions.

# Principles of the ESAOTE Policy on interactions with Healthcare Organizations and Healthcare Professionals

The interaction between all Group Companies and Healthcare Professionals/Healthcare Organisations is an important feature in achieving mission to make safe, innovative and reliable technology and related services available to more people. The development of innovative medical devices and technologies and the improvement of existing products require collaboration with Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services. The safe and effective use of medical technology and related services requires to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support. The support of medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction all Group Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the relationship.

For such purpose, the following **ten general principles** must always be abided in any case of interaction with Healthcare Professionals/Healthcare Organisations:

- All the interactions must be transparent and comply with national and local laws, regulations or professional codes of conduct.
- 2. Interaction with Healthcare Professionals/Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of our products.
- 3. All the materials and information shared with Healthcare Professionals/Healthcare Organisations must be accurate, balanced, fair, objective, complete, not misleading and be substantiated by the appropriate evidence.

 Never provide, offer or promise anything of value to improperly influence a decision affecting any of our business, including any decision regarding the purchase and supply of our products.

Anything provided of value must be given without expectation of reciprocity, explicit or implied obligation, favour, or action in return.

- 5. Always consider and resolve any potential conflict of interest which has been identified in interactions with Healthcare Professionals/Healthcare Organisations. A conflict is any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision.
- 6. There must always be a real, genuine and legitimate business need for our interactions with Healthcare Professionals/Healthcare Organisations.
- 7. Anything provided of value must be appropriate in the circumstances, be reasonable in value when measured by local market conditions and must be infrequent when combined with all types of benefits (for example, fees for service and hospitality) provided cumulatively. The assessment of whether the benefits are infrequent, must be made on a case by case basis. To determine frequency, we need to assess whether the additional benefit (when combined with all previous benefits provided, usually within a 12 month period) might undermine the independence, and/or improperly influence the decision making, of the recipient for the benefit of our business. Any fee for service must not exceed the fair market value of the services provided.
- 8. Anything provided of value must be given openly and transparently and must be accurately recorded in our books and records. It must be provided in a manner that would not result in adverse reputational impact or embarrassment to us if publicly disclosed.
- All payments to Healthcare Professionals/Healthcare Organisations must be publicly disclosed where required under applicable law and industry standard to which we adhere.
- 10. For interactions with Healthcare Professionals/Healthcare Organisations, such as where services are performed by a Healthcare Professional for or on behalf of us, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Company.

# INFORMATION NOTICE PURSUANT TO ART. 13 OF THE REGULATION (EU) 2016/679 AND TO THE APPLICABLE LAWS AND REGULATIONS

1. Pursuant to the General Data Protection Regulation (hereinafter "GDPR") and to the applicable laws and regulations, ESAOTE S.p.A., with legal address in Genoa (Italy), Via Enrico Melen, 77, (hereinafter, "the company") as a Data Controller of the HCP personal data and in the capacity of legal representative, hereby informs the HCP regarding the processing of the HCP personal data.

#### 2. Processing purposes.

The HCP personal data and, where appropriate, the HCP relatives' personal data may be processed in relation to the activities carried out by the company for the following purposes:

- fulfilment of legal and regulatory requirements. The provision of the HCP personal information is mandatory to pursue this purpose and an explicit consent is not required.
- b) fulfilment of purposes strictly related to the management and the execution of the contract. The provision of the HCP personal information is discretionary, anyway a refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described in the contract to which the privacy notice is attached.
- c) functional to Esaote activities:
  - promotion and selling of Esaote's products or services (executed through the
    provision of commercial information related to economic, administrative and
    commercial activities of the Company via phone, mail, carriers, fax, e-mail and
    through the private area of our website.
  - performance of surveys to assess the satisfaction of the customers through interviews or questionnaires;
  - processing of studies and market researches performed by Esaote via interviews or questionnaires.

Such processing activities will not involve special categories of personal data.

#### 3. Processing legal grounds.

The processing of the HCP personal data carried out by the company, as detailed for the purposes a) and b), is necessary to execute the obligations arising from the present contract. The legal ground to perform the activities detailed at the purpose c) is the HCP explicit consent.

## 4. Processing methods.

In relation with the abovementioned purposes, data are processed either manually (processing of documents and paper documents) and/or with computer methods and procedures, only for the purposes for which they were collected and ensuring data security and confidentiality according to what defined in the policies that transpose the applicable legislation.

Data processing shall be carried out within the scope and with the arrangements envisaged by the Data Protection Authority and includes data collection, recording, retention, rectification, communication, erasure, diffusion, etc.

5. Obligatory nature of providing the requested data.

The provision of the HCP personal information is mandatory, with regards to the purpose a), and discretionary, with regards to the purposes b) and c).

A refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described at the purpose b), and thus to perform the contractual relationship.

The consent for the activities detailed at the purpose c) is mandatory.

#### 6. Data retention.

The HCP data will be processed and kept for no longer than is necessary for the purposes for which data are collected. The HCP personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes and for a time defined by law.

With regards to the purpose c), the HCP data will be maintained in a specific database no longer than 10 years.

#### 7. Communication and disclosure of personal data

The HCP personal data may be communicated to Public Authorities, pursuant legal obligations, and to external parties involved in the execution of the purposes detailed above, with specific detail to:

- welfare and social services;
- advisors, partners and freelances;
- companies of Esaote Group;
- banks and/or credit institutions;
- insurance institutions.

Data will not be communicated to other parties, nor will be disclosed without the HCP express consent.

#### 8. Data subjects' rights.

The Regulation identifies in art. 15-22 distinct rights that the data subject can exercise against the data controller. These rights are right of access to personal data, right to rectification, to erasure, right to restriction of processing, right to data portability, right to object, right to lodge a complaint to the Authority.

Requests should be sent to: privacy.esaote@esaote.com

#### 9. Data controller.

The Data Controller is Esaote S.p.A., with legal address via Enrico Melen 77, 16152 Genova, Italia.

Our employees and staff are authorized to process personal data in relation to their tasks, roles and responsibilities. Thus, they have the right to process the HCP personal data within the limits of their competences and pursuant to the instructions given by the data controller.

#### 10. Data Protection Officer (DPO)

The Data Protection Officer is Gabriele Faggioli and his contact references are: dpo.esaote@esaote.com.

# Anonymization of personal and special patient data

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#### 1. Purpose

The aim of these instructions is to describe how to anonymise personal and special patient data, as required in particular by the document "Rules for the processing of personal data and special data during R&D activities", that gives the instructions to which the R&D personnel must scrupulously comply, in order to correctly process personal and particular patient data in accordance with the European Regulation (EU) 2016/679 of 27 April 2016 on the protection of personal data (GDPR).

#### 2. Applicability

These instructions apply to the following cases:

- Exams acquired by the Esaote MRI systems.
- Exams acquired by the Esaote U/S systems.
- Exams acquired by Esaote or other systems and exported in DICOM format.

#### 3. General concepts

Anonymisation, that is de-identification of the exams, is required to avoid exposing personal data and special data, as described by GDPR, to any data breach, while maintaining the capability to use them for R&D, marketing and service purposes.

The de-identification algorithms implemented in the Esaote MRI and ultrasound systems have been designed with the aim to avoid that the de-identified exams can be referred to the original patients. In any case, any anonymisation process is always subject to flaws, and some apparently irrelevant information that remains on the header of the images, or on the pixels themselves (for example, text comments) could make possible, in very particular cases, the identification of the physical person the exam belongs to. For this reason the Esaote personnel has to verify carefully that the anonymisation process is safe enough for the particular exams they are applying it.

In case for any reason the anonymisation cannot be applied, or cannot be safe enough, you need to reduce the number of exported images to the minimum necessary, use when possible an encrypted USB pen drive or an encrypted export, delete them as soon as they are not necessary anymore, and carefully scrub the USB pen drive, or destroy the CD-R used to export the original data before the anonymisation.

## 4. Anonymisation from Esaote MRI systems

## 4.1 Anonymisation when exporting

On the current systems, when you need to de-identify one or more exams when exporting them, the following procedure must be used.

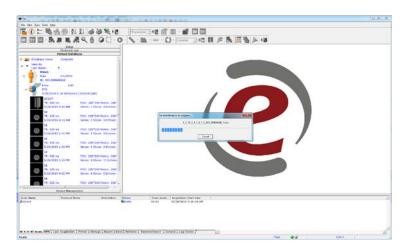
From Opi Patient Tree Tab, select the Patient, Study o Series to export de-identified. Choose from the Tools menu, "Service->Export to device..." item.



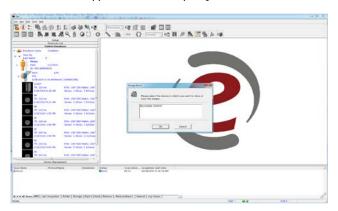
Confirm when asked, that you want to export to DICOM Media:



The de-identification process starts:



At the end, the application asks to specify the device to which de-identified images shall be copied:



# 4.2 Legacy systems

If the exams are contained in a system running a software release that does not support the above procedure, you need to export them in DICOM, and then to anonymise the exported data as described in the chapter 6. Do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

#### 5. Anonymisation from Esaote ultrasound systems

The exams contained in the internal database of the Esaote ultrasound systems can be anonymised using the procedure described in the following paragraph 5.1, when possible.

Otherwise you can anonymise the exams by exporting them in Multimedia format (AVI, BMP, JPG etc.), see the following paragraph 5.2.

To get the complete de-identification of the exams exported in Native format see the following paragraph 5.3.

To get the complete de-identification of the exams exported in DICOM format see the chapter 6.

#### 5.1 Local anonymisation

On some of the current systems, when you need to de-identify one exam leaving it in the local database, the following procedure can be used.

Select the exam to anonymise, open it, press Patient ID and in the panel press the "Anonymize" button. The patient data are immediately de-identified.

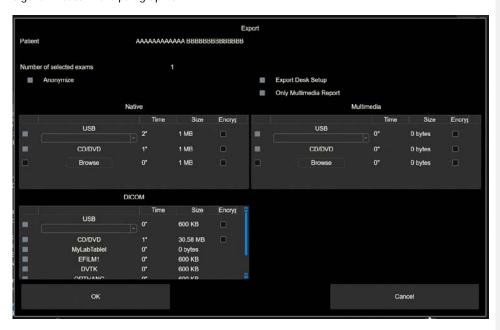


In case the above button is not available, export the exam(s) using the procedure described at paragraph 5.3 and remove them from the local database.

#### 5.2 Multimedia anonymisation

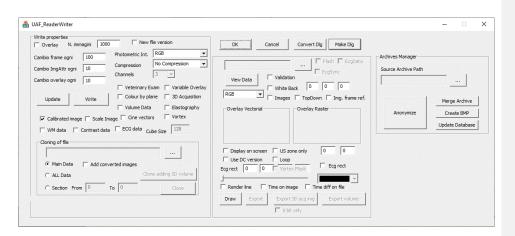
When you need to de-identify one exam exporting it in multimedia format (AVI, BMP, JPG etc.), the following procedure must be used.

Select the exams to anonymise, press Export, and from the Patient ID panel press the "Anonymize" button. The patient data are exported in the selected format(s) using the same algorithm used in the paragraph 0.



# 5.3 Native format anonymisation

The complete anonymisation of one or more exams exported in Native format can be done using the software "UAF Reader/Writer", provided by Esaote as P/N SWE000993. You need to obtain the latest release, to install it in you personal computer (running Windows 10) and to launch it. The following panel appears:



In the "Archives manager" section select, for "Source Archive Path", the folder where the exported database is stored, and press "Anonymize": the exported database will be fully anonymised, so you can import it in a compatible Esaote ultrasound system, using the Database rebuild function.

After the anonymisation, do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

#### 6. Anonymisation of DICOM exams

Anonymisation of DICOM exams (exported from any Esaote system) should be performed using the tool DicomCleaner. It is a free open source tool with a user interface for importing, "cleaning" and saving sets of DICOM instances (files); it has been designed by David Clunie, one of the major DICOM experts in the world, and is produced by his company, PixelMed. The tool can be freely downloaded from

http://www.dclunie.com/pixelmed/software/webstart/DicomCleanerUsage.html

where you can also find all the needed information about its usage. The tool can also blank pixel areas that contain personal information.

After the anonymisation, do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

#### 7. Annexes

Not Applicable

#### 8. Revision info

First issue

# COLLABORATION (AND LOAN FOR USE) AGREEMENT FOR MEDICAL AFFAIRS OBJECTIVES

- This standard is attached to Esaote Group Key Opinion Leaders Guidelines;
- This standard is ruled under Italian Law;
- The responsibility of ensuring localization of this standard under local applicable laws stays within the relevant company in Esaote Group.

This page is merely explanatory and must be removed from the agreement draft.

## COLLABORATION (AND LOAN FOR USE) AGREEMENT

#### **BETWEEN**

ESAOTE S.p.A., with headquarters in Via Enrico Melen, 77 - 16152, Genoa, Italy, Taxpayer Identification and VAT Code No. 05131180969, hereinafter simply referred to as **ESAOTE**, represented by its Representative [•], endowed with the necessary powers,

#### **AND**

[•], hereinafter simply referred to as **Healthcare Organization** ("HCO")

#### **WHEREAS**

- 1. The HCO has several years of international experience in the field of [•] [pls provide the full and correct details of the specific field of activity and research interest of the site].
- 2. The HCO, in the name of [•] [pls specify in clear the details of the individual taking responsibilities and liability for the initiation and implementation of a clinical investigation], is planning to carry out a clinical study in the field of [•] [pls specify the field of activity].
- 3. ESAOTE has for years been engaged in the development of innovative [Ultrasound/MRI] medical devices incorporating [•] [pls specify the technology of interest for the clinical project] technologies for the assessment of [•] [pls specify].
- 4. ESAOTE is interested in collaborating with the HCO for the development of such clinical study activity, making available its knowledge and equipment, on a temporary basis and under the conditions herein laid out, to the collaboration activities herein agreed.
- 5. ESAOTE holds, and shall continue to hold for the entire duration of this Agreement, all the authorizations and licenses necessary to own full rights over the trademark (word and figurative) reproduced in Attachment 3 (hereinafter the "Trademark"), and to grant rights under this Agreement. ESAOTE wishes to promote its products, business, and image, within the territory, in compliance with its ethical principles.
- 6. Also pursuant to Anac resolution n° 831/2016, the Parties specifically declare and acknowledge that no compensation shall be granted to ESAOTE pursuant to this Agreement and ESAOTE will loan the use of the equipment free of charge.

# THE PARTIES THEREFORE AGREE AND COVENANT AS FOLLOWS Article 1 - Recitals

The Recitals are an integral and substantive part to this Agreement.

#### Article 2 - Object

The Clinical Study (the "Study") will follow the detailed protocol attached to this sub-ATTACHMENT 1 (the "Protocol") on [•] [pls provide in clear the Title of the clinical study].

#### Article 3 - Performance of the activities

Detailed procedures for the Study are provided in the Protocol in sub-ATTACHMENT 1. The HCO represents and warrants to have completed all the necessary procedures and to have obtained all the necessary authorizations to sign and perform this Agreement in compliance with the applicable laws and regulations.

#### Article 4 - Activities of the HCO

The HCO agrees to:

- 1. Indicate, in every type of documentation produced, that the activities have been carried out with ESAOTE equipment.
- 2. Maintain appropriate records in relation to the provision of the Equipment by ESAOTE, including proof of receipt for any Equipment delivered by ESAOTE and proof of delivery of any Equipment returned to ESAOTE.
- 3. Provide the following reports within the timeframes indicated below:

Frequency	Report
6 months	- Semiannual report, calculated starting
	on the date of validity of this
	Agreement.
	- Final Report on the performance of the
	activities.

4. Enable the members of staff of ESAOTE, as previously communicated by ESAOTE, to carry out jointly agreed visits for the purpose of assisting in the activities and reaching the objectives detailed under ATTACHMENT 1 hereto.

#### Article 5 - Loan for Use

For the purpose of assisting in the activities, ESAOTE makes available to the HCO, under a free-of-charge Loan for Use, one piece of equipment, with CE marking, in compliance with the European directive on medical devices, and described in ATTACHMENT 2 herein ("Equipment"), and agrees to provide introductory training for the purpose of using the Equipment to the doctors who shall make use thereof, with the expected duration of 1 (one) week. The Equipment shall be placed within the facilities of the HCO and shall be used with care and diligence. The HCO shall abstain from any use of the Equipment other than those expressly granted under this Agreement and/or necessary to work on the Study.

The HCO shall bear any costs connected with the use of the Equipment. For the entire duration of this Agreement ESAOTE shall bear all the costs relative to an insurance policy covering against fire and theft, and to the ordinary and extraordinary maintenance of the Equipment. Consumables are expressly excluded.

The HCO shall be held liable for any loss and/or damage to the Equipment caused by the negligence of the users, for any reason whatsoever.

The HCO expressly indemnifies and holds ESAOTE harmless form any liability for damages to persons of things deriving from the use of the Equipment, unless said damages are caused by flaws and/or design and/or manufacturing defects. Pursuant to and by effect of Article 1806 of the Italian Civil Code, the Parties estimate the total value of the Equipment in [to be specifed]. Upon termination of this Agreement, ESAOTE shall remove the Equipment at its sole care and expense.

#### **Article 6 - Publications**

The HCO will be able to disclose the results of the Study through participation in congresses and conferences as well as through scientific publications on primary scientific journal in the field. The HCO undertakes to submit the scientific works in advance to ESAOTE and to receive, as far as possible, its comments in order to best protect the rights of ESAOTE and relevant patents. ESAOTE undertakes to send its comments to the HCO possibly within 60 days from the request.

#### Article 7 - Confidentiality

1. The HCO guarantees that the staff appointed to carrying out the activities shall maintain, towards any non-authorized person, full confidentiality as regards to any information, knowledge on the performance and the status of the Equipment, as well as to any

- confidential document they may become aware of within the scope of this Agreement or any future agreement and/or protocol.
- 2. The HCO agrees to treat as confidential and not to disclose, either directly or indirectly, any information concerning ESAOTE and the products designed by the latter, of which they may gain knowledge during the performance of the activities. Specifically, the HCO acknowledges that such information shall be deemed property of ESAOTE, and agrees:
  - to keep said information as confidential and disclose it exclusively to members of staff of the HCO limited to what is strictly necessary for the purpose of performing the activities, demanding the strictest confidentiality.
  - not to copy, disassemble, or in any way interfere with the hardware and the software of ESAOTE's Equipment.
  - if required by ESAOTE, promptly return every piece of written information and any copy thereof.
- 3. This confidentiality agreement does not apply to any information already in the public domain or which was available to the HCO at a time prior to the signing of this Agreement.
- 4. This confidentiality agreement is binding for the duration of this Agreement and for a period of five (5) years after the termination thereof.

#### Article 8 - Use of the trademark

- ESAOTE grants to the HCO the right to use the ESAOTE Trademark, exclusively in the measure in which the use of the Trademark is necessary to the HCO to work on the study, for the duration and under the condition laid out in this Agreement.
- 2. The HCO shall be entitled to no right to use the Trademark other than those expressly granted herein. In particular, the HCO shall not have the right to transfer and/or grant in any way to any third party the right to use the Trademark, and undertakes to abstain from any conduct and/or from promoting any initiative connected to the Trademark, and, in any case, to the image of ESAOTE, other than those expressly provided under this Agreement, or which may damage in any way the Trademark or the image of ESAOTE.
- 3. The Parties acknowledge and agree that, at any time during the duration of this Agreement, ESAOTE may request the HCO, via written communication, to cease to use the Trademark, or to use a modified or different mark (the "Modified Trademark"), which shall be communicated by the HCO in the same manner.
  - The HCO shall cease to use the Trademark upon receipt of ESAOTE's request and shall refrain from using the Trademark until receipt of a written communication from ESAOTE

requesting otherwise. Should ESAOTE request the HCO to use the Modified Trademark, the HCO shall use the Modified Trademark as soon as reasonably possible, and, in any case, no later than a month after receipt of the notification from ESAOTE. In this case, the costs and expenses required to promptly use the Modified Trademark shall be borne by ESAOTE, by reimbursing the HCO promptly upon receipt of a suitable written evidence of said costs and expenses and a relative invoice.

#### Article 9 - Persons in Charge of the Collaboration

Person in charge of gr project for ESAOTE: the project head appointed by ESAOTE to interact with the HCO shall be [•] [pls insert in clear the Esaote's person in cahrage of the collaboration], who shall liaise with the HCO for anything relating to the performance of the collaboration and of this Agreement.

Person in charge of the activities for the HCO: the scientific project head of the collaboration, and person in charge appointed by the HCO to interact with ESAOTE shall be, [•] [pls specify], who shall liaise with ESAOTE for anything relating to this Agreement, and more specifically, within the scope of the Agreement, sign any formal instrument (report, document, or correspondence).

ESAOTE and the HCO agree to promptly notify in writing the other Party of any variation to the above persons appointed.

The persons appointed for the purpose of the collaboration shall be in charge of organizing one or more training and briefing meetings with ESAOTE's staff on the activities carried out and the results achieved.

#### **Article 10 - Duration**

This Agreement shall be valid from [•] until [•]. Tacit renewal is expressly excluded.

#### Article 11 - Compliance with law and policies

The HCO shall perform the Agreement and shall conduct all the activities in compliance with applicable laws, regulations and professional codes of conduct (including the Assobiomedica code of conduct and COCIR principles).

The management of any relationship and activity involving healthcare professionals who operate for the HCO is under the exclusive responsability of the HCO, including any compensation due or paid to such professionals.

The HCO acknowledges and confirm that Loan for Use of the Equipment does not improperly reward, induce and/or encourage the HCO and/or any HCO's directors, officer or

employee to purchase, lease, recommend, use, supply or procure any ESAOTE's product or service.

In any case the HCO shall conduct the activities in a manner to avoid and, in case, to promptly disclose and resolve any Conflict of Interest which may arise in the interactions between the Parties and/or their directors and officers. For the purpose of this clause "Conflict of Interest" means any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision. The HCO acknowledges that ESAOTE adopted: (i) a Code of Conduct, (ii) an Organization, Management and Control Model in compliance with Legislative Decree No. 231 of 2001, and (iii) a policy regulating the interactions with Healthcare Organizations and Healthcare Professionals whose principles are here attached under "4" (the "Policy"). The provisions of the Code of Conduct and the Organization, Management, and Control Model can be found on the website <a href="https://www.esaote.com">www.esaote.com</a>, and constitute an integral and substantive part to this Agreement.

In the performance of the activities herein set out the HCO agrees to adhere to and comply with ESAOTE's Code of Conduct, the Organization, Management, and Control Model and the Policy, insofar as they are applicable to the HCO, and thus, by signing this Agreement, the HCO also agrees to comply with the provisions therein contained.

In case of violation by the HCO of any obligation set forth under this clause, ESAOTE shall be entitled, pursuant to Article 1456 of the Italian Civil Code, to terminate this Agreement for all purposes of law, and to bring action against the HCO to claim compensation of the relative damages.

# Article 12 - Hygiene and Safety in the Workplace - Mutual Disclosure on Specific Risks and Management of Risks from Interferences

- 1. ESAOTE guarantees full compliance with the obligations provided under Italian Legislative Decree 81/08, as amended, for the purpose of protection of the health and safety of its workers in the work place.
  - Should ESAOTE's staff, in line with the times and as provided in this Agreement, occasionally visit in work environments under the legal control of the HCO, including in areas featuring risks other than those specifically assessed by ESAOTE, the latter undertakes to provide to the HCO all the necessary and sufficient information on the risks connected with ESAOTE's activities, for the purpose of enabling the HCO to analyze possible interferences between works. ESAOTE agrees to provide its full collaboration necessary to such end.

2. In the performance of the activities herein agreed, the HCO agrees to keep ESAOTE informed of the risks present in the areas where ESAOTE's members of staff may operate, promoting a full cooperation and coordination activity, and the drafting of a Single Document for the Assessment of Interference Risks (Documento Unico di Valutazione dei Rischi da Interferenza, or DUVRI) pursuant to Article 26 of the Italian Legislative Decree 81/08, as amended, which is to be deemed an integral and substantive part to this Agreement.

#### **Article 13 - Personal Data Processing**

By executing this Agreement, the HCO, acknowledges to be Data Owner of the data collected, registered, organized and saved in the memory of the Equipment.

In the event that ESAOTE, during the performance of this Agreement carries out any activity relating to the processing of data pursuant to art. 4, par. 2) of the European Regulation 679/2016 - GDPR, the HCO undertakes to promptly appoint ESAOTE as External Processor pursuant to art. 28 of the above mentioned European Regulation, under the following conditions:

#### Data processor shall:

- a) process Personal Data in accordance with and for the specific purposes of the performance of Technical Service Activities and pursuant to the Information Notice attached to the General Terms and Conditions
- b) maintain the highest level of confidentiality about the Personal Data;
- c) ensure that people authorized to the processing of Personal Data under the authority of the Data Processor is bounded to the duty of confidentiality;
- d) train people authorized to process Personal Data under the authority of the Data Processor and provide them with adequate instructions relating to data processing activities, monitoring the compliance;
- e) ensure that adequate technical and organizational measures are implemented to ensure a level of security appropriate to the risk, in accordance with Art. 32 of GDPR;
- f) assist the Data Controller, to the extent applicable, in the execution of the Data Protection Impact Assessment and prior consultation, in accordance with Art. 35 and 36 of the Regulation;
- appoint System Administrators and monitor their activity in compliance with the Provision issued by the Data Protection Authority on November 27, 2008 (and subsequent amendments and additions);
- h) promptly both communicate to the Data Controller criticalities and flaws concerning data protection and indicate whether any instructions received by the Data Controller, in its opinion, violates the GDPR or other provisions relating to data protection;
- i) inform the Data Controller about investigations carried out by the Data Protection Authority or any other Authority that involve Personal Data;
- j) notify the Data Controller any Personal Data breach likely to result in a risk to the rights and freedoms of the data subjects, according to the manner and providing all the

- information pursuant to art. 33 of the GDPR and supporting the Data Controller for the consequent communications to the data subjects referred to in art. 34 of the GDPR;
- k) keep a written record of the processing activities carried out on behalf of the Data Controller pursuant to art. 30 of the Regulation provide to the Data Controller a report showing the status of the activities carried and the measures put in place to comply with GDPR pursuant to art. 30 of the GDPR;
- when the Data Processor needs to transfer Personal Data to a third country or an international organization in compliance with Union or Member State law, it informs the Data Controller of this legal requirement before processing, unless that law prohibits such information on important grounds of public interest;
- m) for the purposes of processing Personal Data for the purposes under letter a) above, in the case where the Data processor intends to make use of Sub-Processors or in the case where any information provided to the Data Controller is to be updated or amended, the Data Processor shall previously inform the Data Controller including the identity, contact details and the relevant activities carried out by the Sub-processors. In case the Data Controller does not make opposition within 5 days from the notification by the data processor, the use of the sub-contractor and appointment of sub-processor shall be authorized.
  - In case of the appointment of Sub-Processor, the Data Processor shall impose on the same the obligations set out in these Conditions. If, furthermore, the Sub-Processor fails to comply with its data protection obligations, the Data Processor retains the entire responsibility for the fulfillment of the obligations of the other party towards the Data Controller.
- delete or return all the personal data after the end of the provision of services relating to the processing and delete existing copies, unless Union or Member State law requires storage of the personal data;
- o) make available to the Data Controller all the information necessary to demonstrate compliance with the obligations referred to in this appointment letter and allow and contribute to the review activities, including inspections, carried out by the data controller or another person appointed by them.

ESAOTE will process the HCO personal data as per the Information Notice here attached under "5".

In addition to the above, at the termination of this Agreement, the HCO undertakes to return the Equipment without any data ownership of which is of the HCO.

It remains understood that ESAOTE will have the right to receive data anonymized according to ESAOTE Procedure here attached under "6" regarding data subjects collected and/or anyhow processed ny means of the System.

ESAOTE will be therefore authorized to freely use anonymized data received and/or obtained as described above in order to improve ESAOTE products and/or services and/or to develop new products and/or services with no obligation to grant anything to the HCO for any reason whatsoever.

To this effect, the HCO declares and acknowledges that ESAOTE anonymization process is legitimate as well as the subsequent use of anonymized data for the abovementioned purposes.

The HCO also declares and guarantees to have all necessary authorizations and consents for for processing personal data to the effect of this Contract.

The HCO undertakes to release ESAOTE from any consequence, loss of action, even carried out by third parties, deriving from the violation by the HCO of the declarations and warranties here described.

#### Article 14 - Governing Law and Jurisdiction

This Agreement is governed under the laws of the Republic of Italy.

Any dispute arising out of or in connection to the interpretation or performance of this Agreement shall be subject to the exclusive jurisdiction of the Court of Genoa, Italy.

Read, confirmed, and signed	
For the HCO	
[Name & Title]	
For ESAOTE	
[Name & Title]	

# ATTACHMENT 1

# PROTOCOL OF THE STUDY

# ATTACHMENT 2

Description of the equipment object to this Agreement as per art. 5- Loan for use

#### COMPANY TRADEMARK AND TRADEMARK USE REGULATION

#### **TRADEMARK**



#### RULES FOR THE OCCASIONAL AND TEMPORARY USE OF THE ESAOTE TRADEMARK

# SECTION 1. - LEGAL OWNERSHIP AND DESIGNATION OF THE TRADEMARK

Esaote is the legal owner of the trademark described in section No. 2 of these rules. Individuals who are granted authorization to make occasional and temporary use of the Trademark expressly recognize that Esaote is the sole legal owner of the Trademark; moreover, they recognize the value and goodwill associated with the trademarks and acknowledge that value and goodwill belong exclusively to Esaote. They further recognize that the right to use the Trademark must be exercised in strict obedience to the conditions and Terms of these rules, and that they will not at any time or in any way acquire any further rights to the trademark, under its use in the forms authorized by Esaote.

#### SECTION 2. - DESCRIPTION OF THE TRADEMARK

The trademark



corresponds to the characteristics described in document No. MAK000115 Ver. 01 "Corporate Identity - The new guidelines for the use of the Esaote Trademark and its applications".

#### SECTION 3. - PURPOSES AND AIMS OF THE TRADEMARK

By means of the Trademark, Esaote intends to pursue the following goals:

- to promote the corporate image;
- to identify technologies, activities, and services generated by the Company;
- to enhance less invasive, more accessible methods of diagnostic imaging, offering, at the same time, higher efficiency standards, such as those developed by Esaote;
- to spread the values of creativity, innovation, and excellence in research and development that are particular to the Company's story.

For these key reasons, the trademark must be protected and safeguarded.

#### **SECTION 4. OWNERSHIP OF THE TRADEMARK**

The Trademark is owned exclusively by Esaote SpA.

Only Esaote has the right to authorize the use of the Trademark by third parties who so request it, specifying the terms, methods and limits of that use.

#### **SECTION 5. USE OF THE TRADEMARK**

Individuals who are granted authorization to make temporary and occasional use of the Trademark undertake:

- to not use the Trademark in any way, not even through a third person, if it is not included in the ways provided by these Rules, by the manual "Guidelines for the use of the Esaote Trademark" or, anyhow, by the forms specifically established at the moment of authorization;
- to not use in any way, even through a third person, distinguishing images, other images, words, or names that are similar to and/or may be confused with the Trademark;
- to not register trademarks or domain names in their own name that incorporate the words, letters, writing, images or colors that characterize the Trademark, nor any trademark that could be confused with that of Esaote or that is based on it or that could be considered derived from it in any way;
- to not make any sort of variation, addition, or graphic, chromatic or literal modification to the trademark, that is, to not use the trademark in connection, combination, or together with other trademarks, names, words, images, symbols, or colors without prior written approval from Esaote;
- to not depict, display, or promote together with the depiction of the Trademark, trademarks referring to or products made by Esaote's competitors;
- to not sub-grant, transfer, or authorize use of the Trademark to third parties, as that use must only be made directly by the individuals authorized by Esaote;
- to not grant to third parties in sub-license or to any other titles the right or power to use the Trademark, even only partially, as granted by Esaote.

Esaote reserves the right to demand suspension of all forms of the Trademark's use at any time, when that use is not made in compliance with the conditions here defined.

Consequently, the user cannot make partial use of the Trademark nor modify it in any way, but must use it in its entirety, and in the shapes, dimensions, graphic depiction, and colors as provided by the manual "Guidelines for the use of the Esaote Trademark", or in any case, in the forms specifically established at the moment of authorization. The Guidelines' duration is unlimited.

#### SECTION 6. DURATION OF THE AUTHORIZATION

The duration of the right to use the Trademark will be determined at the time of authorization, with expiration of all rights of use occuring for that defined period without the necessity of any formal correspondence, except in cases of suspension, revocation, forfeiture, or cancellation, in accordance with the methods described in sections 9, 10, and 11 of these rules.

#### SECTION 7. TRADEMARK PROTECTION

Use of the trademark for activities in contrast with Esaote's constitutional aims is strictly prohibited.

The user recognizes the trademark's prestige and, consequently, undertakes to use the trademark with the utmost care and diligence. As such, all activities carried out by the user while using the Esaote trademark must be performed in such a way so as not to damage Esaote's image or in any way harm the trademark's reputation. In particular, the user agrees not to use the Trademark in a way that is deceptive toward the public.

The user recognizes that the trademark is the exclusive property of Esaote and agrees to immediately inform the same of any third party action or event that may constitute a real or suspected violation of the rights of Trademark ownership, reporting every objection, complaint, or warning related to the use of the Trademark, as well as any falsification that has come to his/her attention.

The user and Esaote will, therefore, lend each other reciprocal collaboration in every effort meant to protect and defend the trademark, subject to Esaote's full autonomy and discretion in the adoption of measures deemed opportune for the purposes above indicated.

Esaote may carry out inspections, directly or via third parties, to ensure the correct use of the trademark.

In accordance with that which is provided by trademark protection law, Esaote has the right to initiate legal proceedings against all those who use the trademark without prior authorization.

#### SECTION 8. NON-AUTHORIZED USE OF THE TRADEMARK

In the case of non-authorized use of the Trademark or use of the Trademark that diverges from the regulations imposed at the time of authorization, Esaote will order immediate cessation of the use, as well as the destruction of all related materials or the interruption of all activities deemed damaging to Esaote's rights, operating in the appropriate central offices for the protection of its rights.

Use of the Trademark by any individual who is not authorized or in divergence with respect to the terms of authorization will be prosecuted by Esaote in accordance with the measures provided by national and international laws for the protection of intellectual property.

#### **SECTION 9. CANCELLATION AND FORFEITURE**

With all other powers of cancellation according to the provisions of the law still holding, noncompliant use of the trademark with respect to the terms and methods established by these Rules, by the Guidelines for the Use of the Esaote Trademark, and by the specific regulations potentially dictated by Esaote at the time of authorization will entail Esaote's right to cancel the

contract pursuant to and in accordance with Art. 1456 of the Italian Civil Code, with the associated automatic rescindment of the authorization.

If Esaote voluntarily ends use of or modifies the Trademark, existing authorizations for the use of the Trademark expire automatically without any expenses charged to Esaote.

In all cases of suspension of the effects of authorization for the use of the Trademark, including expiration, cancellation, and forfeiture, the user is duty bound to immediately cease any activity that involves the use and depiction of the Trademark, and in any case, to cease any distribution of materials in which the Trademark is depicted (such as catalogues, leaflets, labels, websites, or any other communicative material).

#### SECTION 10. REVOCABILITY OF THE AUTHORIZATION

Authorization for the use of the trademark may be unilaterally revoked by Esaote at any time. Anyhow, the contract will be understood as cancelled by operation of law in the case of:

- a) bankruptcy or subjection to other insolvency procedures on the part of the user;
- b) behavior on the part of the user not complying with the established regulations; actions done by the user in the use of the trademark resulting in cases of criminal offence or infractions.

#### **Principles of the ESAOTE Policy**

#### on interactions with Healthcare Organizations and Healthcare Professionals

The interaction between all Group Companies and Healthcare Professionals/Healthcare Organisations is an important feature in achieving mission to make safe, innovative and reliable technology and related services available to more people. The development of innovative medical devices and technologies and the improvement of existing products require collaboration with Healthcare Professionals and Healthcare Organisations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services. The safe and effective use of medical technology and related services requires to offer Healthcare Professionals and Healthcare Organisations appropriate instruction, education, training, service and technical support. The support of medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction all Group Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the relationship.

For such purpose, the following **ten general principles** must always be abided in any case of interaction with Healthcare Professionals/Healthcare Organisations:

- 1. All the interactions must be transparent and comply with national and local laws, regulations or professional codes of conduct.
- 2. Interaction with Healthcare Professionals/Healthcare Organisations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of our products.
- 3. All the materials and information shared with Healthcare Professionals/Healthcare Organisations must be accurate, balanced, fair, objective, complete, not misleading and be substantiated by the appropriate evidence.
- 4. Never provide, offer or promise anything of value to improperly influence a decision affecting any of our business, including any decision regarding the purchase and supply of our products.

Anything provided of value must be given without expectation of reciprocity, explicit or implied obligation, favour, or action in return.

- 5. Always consider and resolve any potential conflict of interest which has been identified in interactions with Healthcare Professionals/Healthcare Organisations. A conflict is any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behaviour, conduct or decision.
- 6. There must always be a real, genuine and legitimate business need for our interactions with Healthcare Professionals/Healthcare Organisations.
- 7. Anything provided of value must be appropriate in the circumstances, be reasonable in value when measured by local market conditions and must be infrequent when combined with all types of benefits (for example, fees for service and hospitality) provided cumulatively. The assessment of whether the benefits are infrequent, must be made on a case by case basis. To determine frequency, we need to assess whether the additional benefit (when combined with all previous benefits provided, usually within a 12 month

period) might undermine the independence, and/or improperly influence the decision making, of the recipient for the benefit of our business. Any fee for service must not exceed the fair market value of the services provided.

- 8. Anything provided of value must be given openly and transparently and must be accurately recorded in our books and records. It must be provided in a manner that would not result in adverse reputational impact or embarrassment to us if publicly disclosed.
- 9. All payments to Healthcare Professionals/Healthcare Organisations must be publicly disclosed where required under applicable law and industry standard to which we adhere.
- 10. For interactions with Healthcare Professionals/Healthcare Organisations, such as where services are performed by a Healthcare Professional for or on behalf of us, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Company.

#### INFORMATION NOTICE PURSUANT TO ART. 13 OF THE REGULATION (EU) 2016/679 AND TO THE APPLICABLE LAWS AND REGULATIONS

**1.** Pursuant to the General Data Protection Regulation (hereinafter "GDPR") and to the applicable laws and regulations, ESAOTE S.p.A., with legal address in Genoa (Italy), Via Enrico Melen, 77, (hereinafter, "the company") as a Data Controller of the HCO personal data and in the capacity of legal representative, hereby informs the HCO regarding the processing of its personal data.

#### 2. Processing purposes.

The HCO personal data and, where appropriate, its relatives' personal data may be processed in relation to the activities carried out by the company for the following purposes:

- a) fulfilment of legal and regulatory requirements. The provision of the HCO personal information is mandatory to pursue this purpose and an explicit consent is not required.
- b) fulfilment of purposes strictly related to the management and the execution of the contract. The provision of the HCO personal information is discretionary, anyway a refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described in the contract to which the privacy notice is attached.
- c) functional to Esaote activities:
  - promotion and selling of Esaote's products or services (executed through the provision of commercial information related to economic, administrative and commercial activities of the Company via phone, mail, carriers, fax, e-mail and through the private area of our website.
  - performance of surveys to assess the satisfaction of the customers through interviews or questionnaires;
  - processing of studies and market researches performed by Esaote via interviews or questionnaires.

Such processing activities will not involve special categories of personal data.

#### 3. Processing legal grounds.

The processing of the HCO personal data carried out by the company, as detailed for the purposes a) and b), is necessary to execute the obligations arising from the present contract. The legal ground to perform the activities detailed at the purpose c) is the HCO explicit consent.

#### 4. Processing methods.

In relation with the abovementioned purposes, data are processed either manually (processing of documents and paper documents) and/or with computer methods and procedures, only for the purposes for which they were collected and ensuring data security and confidentiality according to what defined in the policies that transpose the applicable legislation.

Data processing shall be carried out within the scope and with the arrangements envisaged by the Data Protection Authority and includes data collection, recording, retention, rectification, communication, erasure, diffusion, etc.

#### 5. Obligatory nature of providing the requested data.

The provision of the HCO personal information is mandatory, with regards to the purpose a), and discretionary, with regards to the purposes b) and c).

A refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described at the purpose b), and thus to perform the contractual relationship. The consent for the activities detailed at the purpose c) is mandatory.

#### 6. Transfer of personal data to countries outside the European Union

The data might be processed by other companies of the Esaote Group, which are also based in non-EU countries whose level of data protection has been considered adequate by the European Commission pursuant to art. 45 of the GDPR, or after signing the Standard Contractual Clauses adopted or approved by the European Commission pursuant to art. 46(2)(c) of the GDPR.

A copy of the guarantees may be requested by contacting the data controller at the email address privacy.esaote@esaote.com

#### 7. Data retention.

The HCO data will be processed and kept for no longer than is necessary for the purposes for which data are collected. The HCO personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes and for a time defined by law.

With regards to the purpose c), the HCO data will be maintained in a specific database no longer than 10 years.

#### 8. Communication and disclosure of personal data

The HCO personal data may be communicated to Public Authorities, pursuant legal obligations, and to external parties involved in the execution of the purposes detailed above, with specific detail to:

- welfare and social services;
- advisors, partners and freelances;
- companies of Esaote Group;
- banks and/or credit institutions;
- insurance institutions.

Data will not be communicated to other parties, nor will be disclosed without your express consent.

#### 9. Data subjects' rights.

The Regulation identifies in art. 15-22 distinct rights that the data subject can exercise against the data controller. These rights are right of access to personal data, right to rectification, to erasure, right to restriction of processing, right to data portability, right to object, right to lodge a complaint to the Authority.

Requests should be sent to: privacy.esaote@esaote.com

#### 10. Data controller.

The Data Controller is Esaote S.p.A., with legal address via Enrico Melen 77, 16152 Genova, Italia. Our employees and staff are authorized to process personal data in relation to their tasks, roles and responsibilities. Thus, they have the right to process the HCO personal data within the limits of their competences and pursuant to the instructions given by the data controller.

#### 11. Data Protection Officer (DPO)

The Data Protection Officer is Gabriele Faggioli and his contact references are: dpo.esaote@esaote.com.

# Anonymization of personal and special patient data

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# 1. Purpose

The aim of these instructions is to describe how to anonymise personal and special patient data, as required in particular by the document "Rules for the processing of personal data and special data during R&D activities", that gives the instructions to which the R&D personnel must scrupulously comply, in order to correctly process personal and particular patient data in accordance with the European Regulation (EU) 2016/679 of 27 April 2016 on the protection of personal data (GDPR).

# 2. Applicability

These instructions apply to the following cases:

- Exams acquired by the Esaote MRI systems.
- Exams acquired by the Esaote U/S systems.
- Exams acquired by Esaote or other systems and exported in DICOM format.

# 3. General concepts

Anonymisation, that is de-identification of the exams, is required to avoid exposing personal data and special data, as described by GDPR, to any data breach, while maintaining the capability to use them for R&D, marketing and service purposes.

The de-identification algorithms implemented in the Esaote MRI and ultrasound systems have been designed with the aim to avoid that the de-identified exams can be referred to the original patients. In any case, any anonymisation process is always subject to flaws, and some apparently irrelevant information that remains on the header of the images, or on the pixels themselves (for example, text comments) could make possible, in very particular cases, the identification of the physical person the exam belongs to. For this reason the Esaote personnel has to verify carefully that the anonymisation process is safe enough for the particular exams they are applying it.

In case for any reason the anonymisation cannot be applied, or cannot be safe enough, you need to reduce the number of exported images to the minimum necessary, use when possible an encrypted USB pen drive or an encrypted export, delete them as soon as they are not necessary anymore, and carefully scrub the USB pen drive, or destroy the CD-R used to export the original data before the anonymisation.

# 4. Anonymisation from Esaote MRI systems

# 4.1 Anonymisation when exporting

On the current systems, when you need to de-identify one or more exams when exporting them, the following procedure must be used.

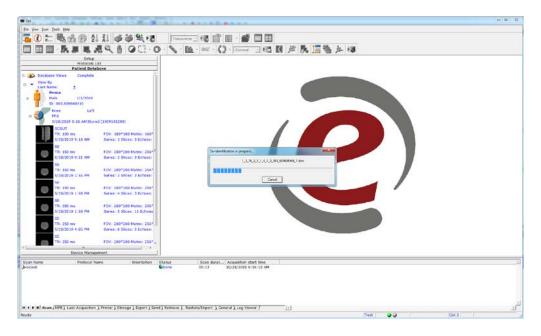
From Opi Patient Tree Tab, select the Patient, Study o Series to export de-identified. Choose from the Tools menu, "Service->Export to device..." item.



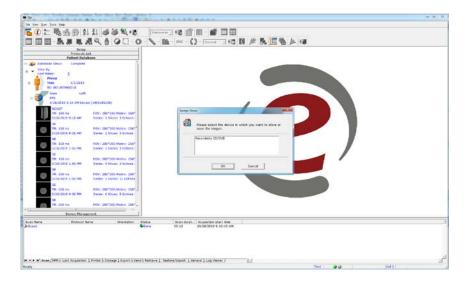
Confirm when asked, that you want to export to DICOM Media:



The de-identification process starts:



At the end, the application asks to specify the device to which de-identified images shall be copied:



# 4.2 Legacy systems

If the exams are contained in a system running a software release that does not support the above procedure, you need to export them in DICOM, and then to anonymise the exported data as described in the chapter 6. Do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

# 5. Anonymisation from Esaote ultrasound systems

The exams contained in the internal database of the Esaote ultrasound systems can be anonymised using the procedure described in the following paragraph 5.1, when possible.

Otherwise you can anonymise the exams by exporting them in Multimedia format (AVI, BMP, JPG etc.), see the following paragraph 5.2.

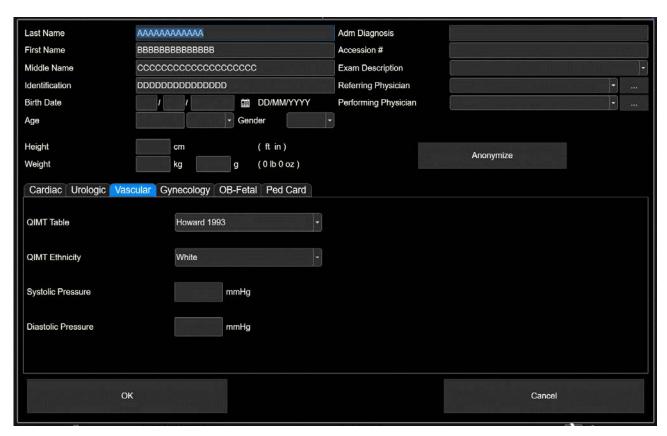
To get the complete de-identification of the exams exported in Native format see the following paragraph 5.3.

To get the complete de-identification of the exams exported in DICOM format see the chapter 6.

# 5.1 Local anonymisation

On some of the current systems, when you need to de-identify one exam leaving it in the local database, the following procedure can be used.

Select the exam to anonymise, open it, press Patient ID and in the panel press the "Anonymize" button. The patient data are immediately de-identified.

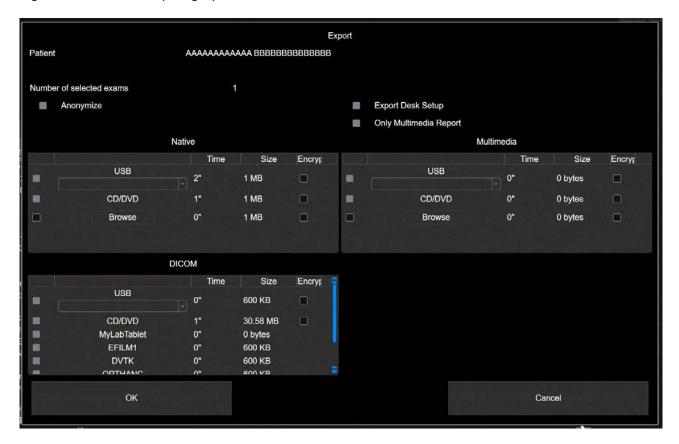


In case the above button is not available, export the exam(s) using the procedure described at paragraph 5.3 and remove them from the local database.

# 5.2 Multimedia anonymisation

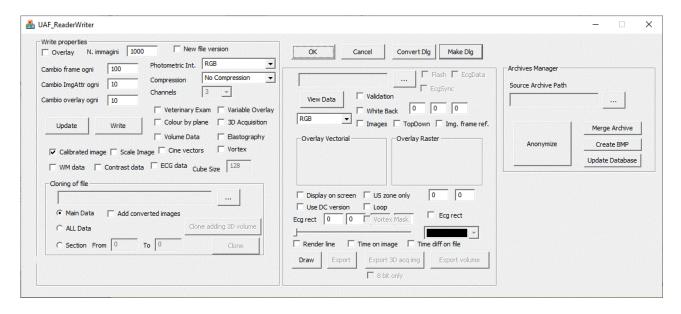
When you need to de-identify one exam exporting it in multimedia format (AVI, BMP, JPG etc.), the following procedure must be used.

Select the exams to anonymise, press Export, and from the Patient ID panel press the "Anonymize" button. The patient data are exported in the selected format(s) using the same algorithm used in the paragraph 0.



# 5.3 Native format anonymisation

The complete anonymisation of one or more exams exported in Native format can be done using the software "UAF Reader/Writer", provided by Esaote as P/N SWE000993. You need to obtain the latest release, to install it in you personal computer (running Windows 10) and to launch it. The following panel appears:



In the "Archives manager" section select, for "Source Archive Path", the folder where the exported database is stored, and press "Anonymize": the exported database will be fully anonymised, so you can import it in a compatible Esaote ultrasound system, using the Database rebuild function.

After the anonymisation, do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

# 6. Anonymisation of DICOM exams

Anonymisation of DICOM exams (exported from any Esaote system) should be performed using the tool DicomCleaner. It is a free open source tool with a user interface for importing, "cleaning" and saving sets of DICOM instances (files); it has been designed by David Clunie, one of the major DICOM experts in the world, and is produced by his company, PixelMed. The tool can be freely downloaded from

http://www.dclunie.com/pixelmed/software/webstart/DicomCleanerUsage.html

where you can also find all the needed information about its usage. The tool can also blank pixel areas that contain personal information.

After the anonymisation, do not forget to carefully scrub the USB pen drive, or to destroy the CD-R used to export the original data before the anonymisation.

# 7. Annexes

Not Applicable

# 8. Revision info

First issue

# SERVICE AGREEMENT WITH HEALTHCARE PROFESSIONALS (HCP)

- This standard is attached to Esaote Group Key Opinion Leaders Guidelines;
- This standard is ruled under Italian Law;
- The responsibility of ensuring localization of this standard under local applicable laws stays within the relevant company in Esaote Group;
- The function initiating the process is responsible for defining the exact and appropriate scope of work of the Agreement.

This page is merely explanatory and must be removed from the agreement draft.

Commentato [SG2]: Please insert place and date

#### Subject: Service Agreement

#### Whereas:

- Esaote is one of the major world manufacturers of medical diagnostic systems recognized at international level as a global leader in [•];
- Esaote aims at offering its existing and potential customers of [•] systems, comprehensive
  information from both technical and clinical perspectives on the features and performances
  of the systems proposed;
- Esaote is interested in having [•] to carry out professional collaboration activities as specified below, regulated as specified below and pursuant to current applicable regulations.

Now therefore, considering the foregoing, Esaote S.p.A. (hereinafter "Esaote") with registered office in Genoa, via Enrico Melen, 77, hereby agrees with [•] (hereinafter the "Healthcare Professional" - HCP) (jointly referred to as the "Parties") to carry out certain professional activities specified in this agreement under the terms and conditions provided for below.

#### 1) Subject

We hereby have the pleasure of inviting the Healthcare Professional to participate to  $[\bullet]$ , organized by  $[\bullet]$ , which will be held in  $[\bullet]$  from  $[\bullet]$ , (hereinafter the "Congress").

During the Congress, the Healthcare Professional will present his personal experience on the [ullet].

The clinical and scientific information relating to [•], which is the subject of Healthcare Professional's scientific activity, will be presented at the [Congress] in dedicated sessions, which will be organized from time to time at the Esaote stand for existing and potential customers visiting the stand.

Participation in the Congress will be governed by the terms set out below and, as far as not expressly provided for, by applicable regulations, including those regarding the authorization of the specific activities by the competent public bodies as applicable.

(hereinafter the "Activities"),

- The Parties expressly agree to exclude any subordination relationship.
- The Healthcare Professional will be free to organize and manage all aspects and methodologies of the Activities with no duty of presence and/or venue and/or time, different from those relating to the achievement of the best result of the Activities, in complete decisional and operative freedom, except for the necessary coordination with ESAOTE.

#### 2) Obligations of the Healthcare Professional

The Healthcare Professional will present at the Congress and disseminate at international level the evolution of [diagnostic techniques for [•] with focus on [•] and illustration of the results obtainable with ESAOTE's products and technologies.

Commentato [SG3]: Please insert HCP's name

Following the participation to the Congress as an expert in the field, the Healthcare Professional will provide to Esaote a written report, a [•].

Specifically, the Healthcare Professional is required to prepare a detailed evaluation of scientific works and technological solutions presented at the Congress that are expressly aimed at analyzing imaging techniques on [•] and any impacts in the clinical and diagnostic field.

### 3) Duration

This Agreement shall be valid for the whole duration of the Congress, from  $[\bullet]$  to  $[\bullet]$ , and until all Activities are completed.

### 4) Consideration and Payment

The Parties hereby agree that Esaote will pay the Healthcare Professional as consideration for the Activities a fee as specified below:

EUR [•] (the "Consideration")

Esaote will pay the Consideration at the conclusion of the Activities, and within 60 days from the date of the invoice issued by the Healthcare Professional. The payment will be made by bank transfer to the following account:

Bank: [●]
Client: [●]
IBAN: [●]
BIC: [●]

### 5) Travel and Accommodation Expenses

ESAOTE will reimburse the Healthcare Professional for reasonable travel and out-of-pocket preapproved expenses incurred by the Healthcare Professional while performing the Activities, within the limitations set forth in the then applicable ESAOTE policy.

In any case all expenses shall be subject to approval in advance by ESAOTE prior to being incurred and the Healthcare Professional must submit copies of appropriate receipts for any such expenses.

No compensation will be paid besides what specified above.

# 6) Confidentiality

The Healthcare Professional agrees to keep confidential any additional information acquired during the performance of this Agreement.

### 7) Intellectual Property

All documentation prepared by the Healthcare Professional when carrying out the Activities will become an exclusive property of Esaote.

## 8) Compliance with law and policies

The Healthcare Professional shall perform the Agreement and shall conduct all the Activities in compliance with applicable laws, regulations and professional codes of conduct (including the Assobiomedica code of conduct and COCIR principles).

The Healthcare Professional acknowledges and confirms that: (A) the Consideration contemplated by this Agreement does not improperly reward, induce and/or encourage the Healthcare

Commentato [SG4]: PLEASE ADD OTHER EXPECTED RESULTS AND OUTPUTS

Professional to purchase, lease, recommend, use, supply or procure any ESAOTE's product or service, and **(B)** he/she has not exercised during the last three years any authoritative and/or negotial power on behalf of a public administration towards ESAOTE.

In any case, the Healthcare Professional shall conduct the Activities in a manner to avoid and, in case, to promptly disclose and resolve any Conflict of Interest which may arise in the interactions between the Parties. For the purpose of this clause "Conflict of Interest" means any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behavior, conduct or decision.

If applicable, the Healthcare Professional will obtain and provide the written consent of his/her employer pursuant to Italian Legislative Decree. 165/2001 at least [one week] in advance of commencing the Activities. The Consultant acknowledges that it will not be entitled to perform the Activities and to receive compensation without obtaining the necessary employer consent, where required under applicable laws.

The Healthcare Professional acknowledges that ESAOTE adopted: (i) a Code of Conduct, (ii) an Organization, Management and Control Model in compliance with Legislative Decree No. 231 of 2001 and (iii) a policy regulating the interactions with Healthcare Organizations and Healthcare Professionals whose principles are here attached under "A" (the "Policy"). The provisions of the Code of Conduct and the Organization, Management, and Control Model can be found on the website www.esaote.com, and constitute an integral and substantive part to this Agreement.

In the performance of the Activities the Healthcare Professional agrees to adhere to and comply with ESAOTE's Code of Conduct, the Organization, Management, and Control Model and the Policy, insofar as they are applicable to the Healthcare Professional, and thus, by signing this Agreement, the Healthcare Professional also agrees to comply with the provisions therein contained.

The Healthcare Professional (1) has not been convicted of any offence involving bribery, corruption, fraud or dishonesty or involved in any other ethical violations or professional misconduct or negligence, (2) is not, so far as the Healthcare Professional is aware, the subject of any investigation, inquiry, enforcement proceedings or legal action by any governmental, administrative, regulatory, industry, professional body or third party regarding such kind of offences, and (3) shall promptly inform in writing ESAOTE should any of such investigation, inquiry, enforcement proceedings or legal action be notified to him/her.

In case of violation by the Healthcare Professional of any obligation set forth under this clause, ESAOTE shall be entitled, pursuant to Article 1456 of the Italian Civil Code, to terminate this Agreement for all purposes of law, and to bring action against the Healthcare Professional to claim compensation of the relative damages.

### 9) Personal Data Processing

Esaote confirms that Healthcare Professional's personal data will be processed pursuant to the European Regulation 679/2016, as per the information notice here attached under "B".

Best regards,

ESAOTE S.p.A.

For acceptance [ullet]

For authorization

[ullet]

## Attachment "A"

### **Principles of the ESAOTE Policy**

### on interactions with Healthcare Organizations and Healthcare Professionals

The interaction between all Group Companies and Healthcare Professionals/Healthcare Organizations is an important feature in achieving mission to make safe, innovative and reliable technology and related services available to more people. The development of innovative medical devices and technologies and the improvement of existing products require collaboration with Healthcare Professionals and Healthcare Organizations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services. The safe and effective use of medical technology and related services requires to offer Healthcare Professionals and Healthcare Organizations appropriate instruction, education, training, service and technical support. The support of medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction all Group Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the relationship.

For such purpose, the following **ten general principles** must always be abided in any case of interaction with Healthcare Professionals/Healthcare Organizations:

- 1. All the interactions must be transparent and comply with national and local laws, regulations or professional codes of conduct.
- 2. Interaction with Healthcare Professionals/Healthcare Organizations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of our products.
- 3. All the materials and information shared with Healthcare Professionals/Healthcare Organizations must be accurate, balanced, fair, objective, complete, not misleading and be substantiated by the appropriate evidence.
- 4. Never provide, offer or promise anything of value to improperly influence a decision affecting any of our business, including any decision regarding the purchase and supply of our products.

Anything provided of value must be given without expectation of reciprocity, explicit or implied obligation, favor, or action in return.

5. Always consider and resolve any potential conflict of interest which has been identified in interactions with Healthcare Professionals/Healthcare Organizations. A conflict is any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behavior, conduct or decision.

- 6. There must always be a real, genuine and legitimate business need for our interactions with Healthcare Professionals/Healthcare Organizations.
- 7. Anything provided of value must be appropriate in the circumstances, be reasonable in value when measured by local market conditions and must be infrequent when combined with all types of benefits (for example, fees for service and hospitality) provided cumulatively. The assessment of whether the benefits are infrequent, must be made on a case by case basis. To determine frequency, we need to assess whether the additional benefit (when combined with all previous benefits provided, usually within a 12 months period) might undermine the independence, and/or improperly influence the decision making, of the recipient for the benefit of our business. Any fee for service must not exceed the fair market value of the services provided.
- 8. Anything provided of value must be given openly and transparently and must be accurately recorded in our books and records. It must be provided in a manner that would not result in adverse reputational impact or embarrassment to us if publicly disclosed.
- 9. All payments to Healthcare Professionals/Healthcare Organizations must be publicly disclosed where required under applicable law and industry standard to which we adhere.
- 10. For interactions with Healthcare Professionals/Healthcare Organizations, such as where services are performed by a Healthcare Professional for or on behalf of us, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the Company.

# INFORMATION NOTICE PURSUANT TO ART. 13 OF THE REGULATION (EU) 2016/679 AND TO THE APPLICABLE LAWS AND REGULATIONS

1. Pursuant to the General Data Protection Regulation (hereinafter "GDPR") and to the applicable laws and regulations, ESAOTE S.p.A., with legal address in Genoa (Italy), Via Enrico Melen, 77, (hereinafter, "the company") as a Data Controller of the HCP personal data and in the capacity of legal representative, hereby informs the HCP regarding the processing of the HCP personal data.

### 2. Processing purposes.

The HCP personal data and, where appropriate, his/her relatives' personal data may be processed in relation to the activities carried out by the company for the following purposes:

- a) fulfilment of legal and regulatory requirements. The provision of the HCP personal information is mandatory to pursue this purpose and an explicit consent is not required.
- b) fulfilment of purposes strictly related to the management and the execution of the contract. The provision of the HCP personal information is discretionary, anyway a refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described in the contract to which the privacy notice is attached.
- c) functional to Esaote activities:
  - promotion and selling of Esaote's products or services (executed through the provision of commercial information related to economic, administrative and commercial activities of the Company via phone, mail, carriers, fax, e-mail and through the private area of our website.
  - performance of surveys to assess the satisfaction of the customers through interviews or questionnaires;
  - processing of studies and market researches performed by Esaote via interviews or questionnaires.

Such processing activities will not involve special categories of personal data.

### 3. Processing legal grounds.

The processing of the HCP personal data carried out by the company, as detailed for the purposes a) and b), is necessary to execute the obligations arising from the present contract. The legal ground to perform the activities detailed at the purpose c) is the HCP explicit consent.

### 4. Processing methods.

In relation with the abovementioned purposes, data are processed either manually (processing of documents and paper documents) and/or with computer methods and procedures, only for the purposes for which they were collected and ensuring data security and confidentiality according to what defined in the policies that transpose the applicable legislation.

Data processing shall be carried out within the scope and with the arrangements envisaged by the Data Protection Authority and includes data collection, recording, retention, rectification, communication, erasure, diffusion, etc.

### 5. Obligatory nature of providing the requested data.

The provision of the HCP personal information is mandatory, with regards to the purpose a), and discretionary, with regards to the purposes b) and c).

A refuse in the provisioning of such information results in the impossibility for Esaote to execute the services described at the purpose b), and thus to perform the contractual relationship. The consent for the activities detailed at the purpose c) is mandatory.

### 6. Transfer of personal data to countries outside the European Union

The data might be processed by other companies of the Esaote Group, which are also based in non-EU countries whose level of data protection has been considered adequate by the European Commission pursuant to art. 45 of the GDPR, or after signing the Standard Contractual Clauses adopted or approved by the European Commission pursuant to art. 46(2)(c) of the GDPR.

A copy of the guarantees may be requested by contacting the data controller at the email address privacy.esaote@esaote.com

### 7. Data retention.

The HCP data will be processed and kept for no longer than is necessary for the purposes for which data are collected. Your personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes and for a time defined by law.

With regards to the purpose c), the HCP data will be maintained in a specific database no longer than 10 years.

### 8. Communication and disclosure of personal data

The HCP personal data may be communicated to Public Authorities, pursuant legal obligations, and to external parties involved in the execution of the purposes detailed above, with specific detail to:

- welfare and social services;
- advisors, partners and freelances;
- companies of Esaote Group;
- banks and/or credit institutions;
- insurance institutions.

Data will not be communicated to other parties, nor will be disclosed without your express consent.

### 9. Data subjects' rights.

The Regulation identifies in art. 15-22 distinct rights that the data subject can exercise against the data controller. These rights are right of access to personal data, right to rectification, to erasure, right to restriction of processing, right to data portability, right to object, right to lodge a complaint to the Authority.

Requests should be sent to: Esaote.privacy@esaote.com.

## 10. Data controller.

The Data Controller is Esaote S.p.A., with legal address via Enrico Melen 77, 16152 Genova, Italia. Our employees and staff are authorized to process personal data in relation to their tasks, roles and responsibilities. Thus, they have the right to process the HCP personal data within the limits of their competences and pursuant to the instructions given by the data controller.

### 11. Data Protection Officer (DPO)

The Data Protection Officer is Gabriele Faggioli and his contact references are: dpo.esaote@esaote.com.



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Management of Interactions with Healthcare Organizations and Healthcare Professionals

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Management of Interactions with Healthcare Organizations and Healthcare Professionals

### 1 SCOPE AND PURPOSE

This Procedure on the Interactions Interactions with Healthcare Organizations ("**HCO**") and Healthcare Professionals ("**HCP**") is part of the Esaote Anti-Corruption Regulations provided for under the Management System Guideline Anti-Corruption.

The purpose of this Procedure is to provide indications on how to manage in a transparent a clear way the relationship with Healthcare Professionals (HCPs) and/or Healthcare Organizations (HCOs) thus reinforcing Esaote commitment to endorse and apply the best practices to promote its ethical dealings in the Healthcare sector.

### 2 APPLICATION

These Guidelines apply to all Functions that are in contact with HCP and HCO for clinical-related activities relevant to the medical devices manufactured by Esaote, wherever it is applied. Thus including all activities carried out by full-time and part-time employees, contractors or interim workers.

### 3 DEFINITIONS

To the effect of this Procedure, the following terms are intended as follows:

**GROUP COMPANIES OR COMPANY**: Esaote S.p.A. and its Subsidiaries.

**HEALTHCARE ORGANIZATION (HCO):** Healthcare Organizations are intended to be medical, scientific and research institutions, such as hospitals, private clinics and medical offices, universities.

Center that provides health services such as diagnosis of diseases, surgical operations, treatment and recovery of patients. They may also perform research and teaching activities.

[Code of Ethics, Assobiomedica 2018]

[MedTech Europe Code of Ethical Business Practice 2018]

[COCIR Code of Conduct 2018]

**HEALTHCARE PROFESSIONALS (HCP):** Healthcare Professionals are intended to be persons associated with either a specialty or a discipline, and who are qualified and allowed by regulatory bodies to provide a healthcare service to a patient, such as a medical doctor, a technologist, a physician, a sonographer, an engineer.

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Management of Interactions with Healthcare Organizations and Healthcare Professionals

[Code of Ethics, Assobiomedica February 2018]

**ESAOTE ANTI-CORRUPTION REGULATIONS**: Esaote MSG and Esaote Procedures finalized to prevent bribery-related risks.

It is responsibility of each single process owner of the relevant MSG to update the regulations (or to issue new regulations) concerning the subjects listed above, also to ensure compliance with this MSG. In defining such regulations, the Esaote Compliance Officer must be consulted.

### 4 GENERAL GUIDING PRINCIPLES

The interaction between all Group Companies and Healthcare Professionals/Healthcare Organizations is an important feature in achieving Esaote objectives to make safe, innovative and reliable technology and related services available to more people. The development of innovative medical devices and technologies and the improvement of products require collaboration with Healthcare Professionals and Healthcare Organizations. Innovation and creativity are essential to the development and evolution of medical technologies and/or related services. The safe and effective use of medical technology and related services requires to offer Healthcare Professionals and Healthcare Organizations appropriate instruction, education, training, service and technical support. The support of medical research and education, serves to enhance Healthcare Professionals' clinical skills and thereby contribute to patient safety and increase access to new technologies and/or related services.

In each such interaction all Group Companies must continue to respect the obligation of Healthcare Professionals to make independent decisions regarding treatment and safeguard the environment in which the interaction takes place to ensure the integrity of the relationship.

For such purpose, the following ten general principles must always be abided in any case of interaction with Healthcare Professionals/Healthcare Organizations:

- 1. All the interactions must be transparent and comply with national and local laws, regulations or professional codes of conduct.
- 2. nteraction with Healthcare Professionals/Healthcare Organizations must not be misused to influence through undue or improper advantages, purchasing decisions, nor should such interaction be contingent upon sales transactions or use or recommendation of Esaote products.
- 3. All the materials and information shared with Healthcare Professionals/Healthcare Organizations must be accurate, balanced, fair, objective, complete, not misleading and be substantiated by the appropriate evidence.
- **4.** Never provide, offer or promise anything of value to improperly influence a decision affecting any of Esaote business, including any decision regarding the purchase and supply of Esaote products.

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Management of Interactions with Healthcare Organizations and Healthcare Professionals

Anything provided of value must be given without expectation of reciprocity, explicit or implied obligation, favor, or action in return.

- 5. Always consider and resolve any potential conflict of interest which has been identified in interactions with Healthcare Professionals/Healthcare Organizations. A conflict is any situation which might undermine, influence or otherwise compromise the independence or impartiality of a person's behavior, conduct or decision.
- **6.** There must always be a real, genuine and legitimate business need for our interactions with Healthcare Professionals/Healthcare Organizations.
- 7. Anything provided of value must be appropriate in the circumstances, be reasonable in value when measured by local market conditions and must be infrequent when combined with all types of benefits (for example, fees for service and hospitality) provided cumulatively. The assessment of whether the benefits are infrequent, must be made on a case by case basis. To determine frequency, we need to assess whether the additional benefit (when combined with all previous benefits provided, usually within a 12 month period) might undermine the independence, and/or improperly influence the decision making, of the recipient for the benefit of our business. Any fee for service must not exceed the fair market value of the services provided.
- **8.** Anything provided of value must be given openly and transparently and must be accurately recorded in Esaote books and records. It must be provided in a manner that would not result in adverse reputational impact or embarrassment to Esaote, if publicly disclosed.
- **9.** All payments to Healthcare Professionals/Healthcare Organizations must be publicly disclosed where required under applicable law and industry standard to which we adhere.
- **10.** For interactions with Healthcare Professionals/Healthcare Organizations, such as where services are performed by a Healthcare Professional for Esaote or on behalf of Esaote, there must be a written agreement setting out, inter alia, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by Esaote.

# **ESAOTE GROUP**

GUIDELINES
ON
MANAGEMENT OF

**CONFLICTS OF INTEREST** 



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# GUIDELINES ON MANAGEMENT OF CONFLICTS OF INTEREST MANAGEMENT

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### 1 Purpose

This document (the "Guidelines on Conflicts of Interest Management") illustrates the regulation adopted by Esaote Group ("Esaote" or the "Group") for the identification and management of situations and/or transactions which may involve a real or potential Conflict of Interest (as defined below).

More in detail, the Guidelines on Conflicts of Interest Management provide global standards ensuring that any director, officer, manager, and employee, including temporary staff, as well as service providers not purely occasional, including those organized in the form of a company with which Esaote entered into a contractual relationship, within Esaote Group (jointly, the "Relevant Persons") acts free from any personal activities, interests and/or relationships which may interfere (or appear to interfere) with the exercise of an objective and sound judgment in doing what is in the Group's best interest.

The purpose of the Guidelines on Conflicts of Interest Management is to help all the Relevant Persons to identify and deal any of such situations and/or transactions in order to allow them to be managed as valid and binding, free from any biased business judgement and decision-making process, and not influenced, directly or indirectly, by any Relevant Persons' undue personal interests - either influence - which may give rise to a Conflict of Interest (as defined below) or either the appearance of such a conflict.

### 2 SCOPE OF APPLICATION

The Guidelines on Conflicts of Interest Management align with Esaote's Code of Conduct<sup>1</sup> as well as the relevant set of corporate values, general principles and policy guidelines in relation to the personnel and is without any prejudice to the provisions contained thereunder.

All Relevant Persons are subject to the Guidelines on Conflicts of Interest Management.

Such set of rules and procedures are in line with Esaote's corporate policies based on the values of collaboration, diligence, integrity, loyalty, professionalism, responsibility and transparency.

# 3 COMMON TERMS AND DEFINITIONS

Unless otherwise defined in the Guidelines on Conflicts of Interest Management, terms and definitions used with the initial letter capitalized shall be deemed to have the

<sup>&</sup>lt;sup>1</sup> Reference is made to page 33 (*Conflicts of interest*) of Esaote's Code of Conduct (available at <a href="https://www.esaote.com/fileadmin/user\_upload/Download/code-of-conduct-2016.pdf">https://www.esaote.com/fileadmin/user\_upload/Download/code-of-conduct-2016.pdf</a>).

following meaning, which are valid whether used in the singular or plural form:

# **Closely Related Persons**

(i) A Relevant Person's family members (such as spouse, or domestic partner, children, stepchildren, parents, siblings and all other relatives by blood or by law); (ii) persons with whom a Relevant Person has or had a relationship, even without continuously living together, that, in the Relevant Person's opinion, may determine a non-objective and non-balanced judgement in performing what is in the best interest of the Group; (iii) those living in the same household as the Relevant Person; (iv) persons with whom the Relevant Person may have developed a meaningful social or business relationship outside of his/her work; (v) a legal person, trust or partnership the managerial responsibility of which are discharged by the Relevant Person or by any of the persons listed under numbers from (i) to (iv) above, which is directly or indirectly controlled by any such person, or the economic interest of which are substantially equivalent to those of any such person.

# Company

means each of the companies which are part of the Esaote Group.

# **Guidelines on Conflicts of Interest Management**

has the meaning set forth under paragraph 1 of the Guidelines on Conflicts of Interest Management.

# **Conflict of Interest**

A situation in which a Relevant Person places his/her personal interests before Esaote's best interest and where such personal interests unduly influence or may influence that Relevant Person's business judgments, decisions and/or actions. Such situations may involve also Closely Related Persons and friends. They include not only actual conflicts of interests (where the Relevant Person faces a real, existing conflict), but also potential conflicts (where the Relevant Person is in or could be in a position which may turn into an actual conflict) and perceived conflicts (where the Relevant Person is or could be in a position which may appear to be a conflict, even though that is not actually the case).

### Esaote Group or the Esaote or the Group

has the meaning set forth under paragraph 1 of the Guidelines on Conflicts of Interest Management

# **Head of Function**

The head of a function.

### **Relevant Person**

has the meaning set forth under paragraph 1 of the Guidelines on Conflicts of Interest

## Management.

# Subsidiary

Any company, affiliate, entity (including an unincorporated entity such as a partnership) which is directly or indirectly, individually or jointly, controlled by Esaote S.p.A. in Italy and abroad.

# Responsible Manager

The line manager directly responsible for the Relevant Persons' work from a business and/or organizational perspective or the subject who receives of the Relevant Persons' services.

## 4 CATEGORIES OF CONFLICT AND PROCEDURES

# 4.1 Common Principles and Rules

As part of their employment relationship with Esaote, the Relevant Persons have a contractual obligation of loyalty towards their employer. Accordingly, each Relevant Person shall avoid any Conflict of Interest with Esaote, which means he/she shall take all necessary and/or appropriate actions, decisions, measures in order to ensure that a Conflict of Interest does not arise, or does not have the risk to occur.

Esaote fully respects the Relevant Persons' rights and therefore it is not willing to interfere with their choices and personal lives. In any case, the Relevant Persons' duty and responsibility to avoid all kind of Conflict of Interests is of vital importance for enhancing the integrity and sustainability of Esaote's business worldwide as well as for increasing mutual trust and support amongst colleagues themselves and in their relationship with Esaote's stakeholders.

In general, the Guidelines on Conflicts of Interest Management consist of the following steps:

(i) Disclosure of Conflict of Interest: any Relevant Person who has, directly or indirectly through a Closely Related Person, a Conflict of Interest with respect to any agreement, contract, relationship and/or transaction whatsoever in which Esaote (including, for the avoidance of doubt, any Company) is a party to, shall disclose to its Supervisor such Conflict of Interest as soon as such situation is known to the Relevant Person by giving clear information on the origin, nature and all other relevant facts of such Conflict of Interest. This latter shall also refrain from any action affecting Esaote's participation in such agreement, contract, relationship and/or transaction. In case it is not clear whether a Conflict of Interest exists, the Relevant Person shall disclose all circumstances to the Responsible Manager, who will determine whether the Conflict of Interest exists and is therefore subject to

the Guidelines on Conflicts of Interest Management. Should the Responsible Manager deem the organizational and administrative arrangements of Esaote insufficient to prevent – with reasonable certainty – the risk of damaging the Group's best and/or Esaote clients' best interests, prior to taking any action, the Responsible Manager shall inform the Legal, Governance & Compliance function clearly of the origin, nature and all other relevant facts of the Conflict of Interest, so that the Legal, Governance & Compliance function can make an informed decision on the agreement, contract, relationship and/or transaction in which Esaote is a party to.

(ii) Addressing the Conflict of Interest: is the process of identifying and implementing strategies and practices to minimize the risks associated with the disclosed Conflict of Interest. On this purpose, the Relevant Persons' Responsible Manager will decide the best way to mitigate potential risks to the business interests and reputation of Esaote (for example by excluding the Relevant Person from any role where he/she can make decisions about or influence the outcome a specific activity which involves Esaote).

Addressing a Conflict of Interest is the responsibility of the Responsible Manager. Specifically, Esaote expects the Supervisor to:

- treat the information disclosed by the Relevant Person with appropriate confidentiality and without bias,
- fairly evaluate the Conflict of Interest disclosed by the Relevant Person, including the risks to the business interests and reputation of Esaote,
- if needed, seek guidance from supporting functions, including Corporate Human Resources and Legal, Governance & Compliance,
- make the best decision to address the Conflict of Interest so that possible risks to Esaote are minimized and the personal interests of the Relevant Person are protected as far as possible,
- communicate the decision and its reasons to the Relevant Person and follow up to ensure the Relevant Person understands and complies with it.
- (iii) **Duty to act honestly and fairly**: in performing the working activities, all Relevant Persons act with integrity and according to proper standards of business to ensure that Esaote's best interest is ensured.

# 4.2 Outside employment and/or business activities

This kind of Conflict of Interest includes, but is not limited to, the following circumstances:

(i) any agreement, contract, relationship and/or transaction between Esaote and a

Relevant Person and/or Closely Related Person;

- (ii) any agreement, contract, relationship and/or transaction between Esaote and any company, entity and/or individual competing with Esaote in the rendering of services in which a Relevant Person and/or Closely Related Person has a material financial interest, or is serving as director, officer, employee, partner, agent, associate, trustee, counsel, others;
- (iii) any Relevant Person directly or indirectly, through a Closely Related Person and/or any other company, entity and/or individual, competing with Esaote in the rendering of services or in any other agreement, contract, relationship and/or transaction with a third party;
- (iv) any agreement, contract, relationship and/or transaction between Esaote and any company, entity and/or physical person in the rendering of services in which a Relevant Person and/or a Closely Related Person has a financial or material interest, or is serving as director, officer, employee, partner, agent, associate, trustee, counsel, others;
- (v) any Relevant Person, directly or indirectly, through a Closely Related Person and/or any other company, entity and/or individual in the rendering of services or in any other agreement, contract, relationship and/or transaction with a third party.

In the circumstances pointed out above, the Relevant Person shall not take part in or attempt to influence, directly or indirectly, any decision or any business dealing of Esaote with such companies, entities, and/or individuals in which the Relevant Person and/or the Closely Related Person has any direct or indirect financial interest.

In addition, such Relevant Person shall promptly disclose to his/her Supervisor any direct or indirect interest he/she may have as soon as he/she discovers that Esaote plans to do business with such companies, entities, and/or individuals.

### 4.3 Gifts, gratuities and entertainment

Without prejudice to the provisions set forth under Esaote's Code of Conduct<sup>2</sup> a Conflict of Interest arises in case any Relevant Person directly or indirectly solicits or accepts gifts, entertainment, or other favors from any company, entity and/or individual that:

- (i) does or is seeking business with, or is a competitor of Esaote; or
- (ii) has received, is receiving or is seeking to receive a loan or grant, or to secure other

<sup>&</sup>lt;sup>2</sup> Reference is made to page 31-32 (*Gifts and entertainment*) of Esaote's Code of Conduct (available at <a href="https://www.esaote.com/fileadmin/user\_upload/Download/code-of-conduct-2016.pdf">https://www.esaote.com/fileadmin/user\_upload/Download/code-of-conduct-2016.pdf</a>).

financial commitments and/or economic benefits from Esaote;

(iii) is a charitable organization,

under circumstances where it may be inferred that such action was intended to influence or possibly would influence the Relevant Person in the performance of his/her duties. This does not preclude the acceptance of items of nominal or insignificant value or entertainment of nominal or insignificant value that are not related to any transaction or activity of Esaote.

If a gift is received nonetheless, it shall promptly be returned if it influences or appears to influence the Relevant Person's business judgment. This does not preclude the acceptance of items of nominal or insignificant value which are not related to any agreement, contract, relationship and/or transaction of Esaote.

Accepting meals, travels, entertainment of a non-ordinary, exceptional nature requires the Supervisor's approval.

In any case Esaote Group Gift and Hospitality Policy shall at all time be complied with.

## 4.4 Ownership and personal financial interests

A Relevant Person shall not influence Esaote's decision to place external business with a company or other entity that is owned or controlled by such Relevant Person and/or his/her Closely Related Person, or with a company or entity in which such Relevant Person and/or his/her Related Person appears to influence the Relevant Person's judgement.

Esaote may place external business with such a company or other entity only if the Relevant Person has not influenced Esaote's decision to place business there and such Conflict of Interest has been duly disclosed before.

# 4.5 Personal Workplace Relationships

A Relevant Person shall not be in a supervisory, subordinate, or control relationship (e.g. which may have an influence over conditions of employment) with a Closely Related Persons.

A Relevant Person shall not be involved in any hiring decision regarding Closely Related Persons (including internal/external hiring and internal transfers).

### 5 CONFLICTS OF INTEREST REGARDING DIRECTORS AND STATUTORY AUDITORS

In case of any agreement, contract, relationship and/or transaction whatsoever in which a Director or a standing Statutory Auditor (or any equivalent body in each relevant jurisdiction) of the Company has an interest on his/her own behalf and/or on behalf of

third parties (including but not limited to any Closely Related Persons), the following provisions apply.

Each Director or standing Statutory Auditor (or any equivalent body in each relevant jurisdiction) in a Conflict of Interest situation shall promptly inform the Company's Board he/she is a member of.

The Company's Board of which the conflicted Director or standing Statutory Auditor (or any equivalent body in each relevant jurisdiction) is a member, will carry out a thorough and documented examination, in the investigation and resolution phases, of the reasons for such agreement, contract, relationship and/or transaction, in order to assess the Company's interest in such agreement, contract, relationship and/or transaction, also taking into consideration the implications and advantages deriving from such agreement, contract, relationship and/or transaction as well as the economic/financial benefit(s) and fairness of the relevant terms and conditions, also in light of objective and documented evidence to be provided by the conflicted Director or standing Statutory Auditor upon request of such body.

In any case, before discussing each item on the agenda of the Board meeting he/she is a member of, each conflicted Director and Statutory Auditor (or any equivalent body in each relevant jurisdiction) shall state any interests on his/her own behalf or on behalf of third parties, which he/she may have in the matters or questions to be discussed, specifying the nature, terms, origin and extent. If the person involved is the CEO and if the agreement, contract, relationship and/or transaction falls within his/her competence, he/she will in any case abstain from taking part in such agreement, contract, relationship and/or transaction and will entrust the matter to the Board of Directors, or where the Board of Director is not appointed, to the shareholders meeting of the relevant Company.

### **6** VIOLATIONS AND CONSEQUENCES

Violation of these Guidelines, as well as of relevant principles and connected regulations, such as the Code of Conduct and the Organizational, Management and Control Model adopted by Esaote S.p.A, may trigger the application of disciplinary measures up to and including termination of employment in accordance with the applicable rules in each relevant jurisdiction.

These Guidelines are violated also in the event that i) a Disclosure Form attached to these Guidelines is incomplete, not accurate and untruthful; ii) any change to a situation of conflict already communicated is not reported or iii) any decision taken for the

management of a Conflict of Interest pursuant to art. 4.1 (ii) is not complied with.

### 7 FINAL PROVISIONS

# 7.1 Reporting

Any Relevant Person who learns of a potential misconduct, violation of applicable laws and/or the Guidelines on Conflicts of Interest Management is required to promptly report his/her suspicion to his/her Supervisor in accordance with the Guidelines on Conflicts of Interest Management. As an alternative, <a href="mailto:ethics.report@esaote.com">ethics.report@esaote.com</a> and <a href="mailto:odv@esaote.com">odv@esaote.com</a> are also available to report any relevant event as per above principles.

As stated in Esaote Group Code of Conduct, any Relevant Person who reports a potential misconduct or who provides information or otherwise assists in any inquiry or investigation of potential misconduct will be protected against any retaliation whatsoever.

## 7.2 Confidentiality

Each Relevant Person shall not disclose or use information relating to the business of Esaote for the personal profit or advantage of the Relevant Person and/or a Closely Related Person.

Furthermore, each Responsible Manager shall exercise care not to disclose confidential information acquired in the exercises of the duties provided under the Guidelines on Conflicts of Interest Management on any Conflict of Interest and/or other circumstances or information on the status of a Relevant Person or Closely Related Person except to the extent strictly required under the Guidelines on Conflicts of Interest Management and in compliance with the principles and procedures set forth hereunder.

## 7.3 Implementation

All Relevant Persons are responsible for adhering to the principles and rules set out in the Guidelines on Conflicts of Interest Management.

All Relevant Persons having an employment relationship with Esaote Group, including non permanent staff, shall promptly submit after publication of the Guidelines for Conflicts of Interest Management to Corporate HR Function, the Conflict of Interest Disclosure Form duly completed.

By submitting the Conflict of Interest Disclosure Form, all Relevant Persons having an employment relationship with Esaote Group, including non permanent staff, will inform the Company that no Conflict of Interest situation (potential or real or perceived) exists or alternatively that a situation of Conflict of Interest (potential or real or perceived)

exists so that they comply with the Guidelines for Conflicts of Interest Management.

All Relevant Persons that work within Esaote Group as service providers not purely occasional, shall promptly declare any Conflict of Interest (potential or real or perceived) to Esaote Manager responsible for the service contract.

Heads of Function shall be responsible to ensure that Conflicts of Interests are duly disclosed under their responsibility in their functional area.

Corporate Human Resources function is responsible for ensuring that Conflicts of Interest are disclosed by new hired resources during the hiring process and that the Conflict of Interest Disclosure Form is submitted by the new hires to the Company

It is the responsibility of every Responsible Manager to adhere to the Guidelines on Conflicts of Interest Management within his/her area of functional responsibility, to lead and to provide the wider guidance to the Relevant Persons reporting to him/her.

Annex	
Conflict of Interest Disclosure F	-orm
То:	
Corporate HR /Manager responsible	e for the service contract
From: [to be filled in with the nam	e and position of the Relevant Person]
Date: [dd mm yyyy]	
Re: Declaration on Conflicts of Inte	erest
NO CONFLICT OF INTEREST TO	DECLARE [ ]
I DECLARE THE CONFLICT OF I	NTEREST AS DESCRIBED BELOW: [ ]
Type of Conflict of Interest	
(potential/actual/perceived)	
Description of the situation	
generating a Conflict of	
Interest and of the relevant	
circumstances	
Name of Closely Related Persons involved and type of	
relationship	
(if applicable)	
Other information useful to	
manage the Conflict of	
Interest and/or comments	
I hereby certify that the information my knowledge.	n contained here is true and complete to the best of
I have reviewed, and agree to Management of Esaote Group.	abide by, the Guidelines on Conflicts of Interest
I hereby authorize the use and pr Guidelines on Conflicts of Interest I	rocess of my personal data for the purposes of the Management of Esaote Group.
Signature:	
Date:	