CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Certificate

No. Q5 095545 0015 Rev. 03

Holder of Certificate: **ESAOTE S.p.A.**
Via Enrico Melen 77
16152 Genova
ITALY

Certification Mark:

Scope of Certificate: **Design and development, production, sales, installation and servicing of ultrasonic diagnostic equipment including probes, magnetic resonance diagnostic equipment and standalone software for the area of medical diagnostic imaging. Servicing of general active non implantable medical devices, active medical devices for imaging and active medical devices for monitoring.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 095545 0015 Rev. 03

Report No.: ITA200220014946

Valid from: 2026-11-18
Valid until: 2029-11-17

Date, 2026-07-21

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

ESAOTE S.p.A.
Via di Caciolle 15, 50127 Firenze, ITALY

Design and development of ultrasonic diagnostic equipment including probes for the area of medical diagnostic imaging. Production of ultrasonic probes for the area of medical diagnostic equipment. Sales, installation and servicing of ultrasonic diagnostic equipment including probes, magnetic resonance diagnostic equipment and standalone software for the area of medical diagnostic imaging.
Servicing of general active non implantable medical devices, active medical devices for imaging and active medical devices for monitoring.

ESAOTE S.p.A.
Via Enrico Melen 77, 16152 Genova, ITALY

Design and development of ultrasonic diagnostic equipment for the area of medical diagnostic imaging. Installation and servicing of ultrasonic diagnostic equipment including probes, magnetic resonance diagnostic equipment and standalone software for the area of medical diagnostic imaging.
Sales of ultrasonic diagnostic equipment including probes, magnetic resonance diagnostic equipment and standalone software for the area of medical diagnostic imaging.

ESAOTE S.p.A.
Via degli Olmi 11, 50019 Sesto Fiorentino (FI), ITALY

Production, warehousing, and shipping of ultrasonic diagnostic imaging.
Warehousing and shipping of ultrasonic probes for the area of medical diagnostic imaging.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Certificate

No. Q5 095545 0015 Rev. 03

ESAOTE S.p.A.
Via Multedo di Pegli 2/E, 16155 Genova, ITALY

Design and development, production, installation and servicing of magnetic resonance diagnostic equipment and standalone software for the area of medical diagnostic imaging.
Servicing of ultrasonic diagnostic equipment for the area of medical diagnostic imaging.

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