

Press Release

Esaote obtains EC MDR certification for the new Magnifico Open total-body magnetic resonance system.

The new European Union Medical Devices Regulation (MDR), Regulation (EU) 2017/745, came into force on May 26th, 2021.

Genoa, November 30th, 2021 – Esaote – a leading Italian company in the biomedical sector, in ultrasound, dedicated magnetic resonance imaging and information technology for healthcare – is pleased to announce that the new **Magnifico Open total-body magnetic resonance system** has obtained **EC MDR certification**.

The new certification attests to the **Magnifico Open system's compliance with the requirements of the new European Union Medical Devices Regulation (MDR), Regulation (EU) 2017/745, which entered into force on May 26th, 2021.**

The new regulation, replacing Directive 93/42/EEC on medical devices (MDD) and others, was implemented by the European Parliament to **improve the EU approval system for medical devices**, by imposing strict requirements on both manufacturers and Notified Bodies involved in the conformity assessment of those devices.

The MDR certification for the Esaote Magnifico Open was issued by the internationally recognized **TÜV SÜD certification body**, one of the first Notified Bodies in the world to receive authorization to provide certification according to the new regulation.

The **evaluation criteria** in the new Regulation include more precise and rigorous requirements in terms of the content and scope of the **technical documentation** required for medical devices and for manufacturers' **Quality Management Systems**; for **clinical assessments and investigations**, especially the type, purpose and quality of clinical data; for **product evaluation** and **after-sales surveillance**, which must be guaranteed at all times.

"We're very proud that our new Magnifico Open total-body magnetic resonance system meets the strict regulatory requirements of the MDR," noted Massimo Polignano, Chief Quality Officer at Esaote. *"It is a highly complex process, one we engaged in immediately at the same time as in the process to develop the system itself. It is a new milestone, acknowledging Esaote's constant commitment to bring safe and reliable diagnostic systems to the market, with the utmost respect for the health and protection of users and patients, on whom our everyday work is always focused."*

Magnifico Open – which adds to the range of Esaote products unveiled in 2021 – is an open magnetic resonance system with **the latest technology**. The wide choice of receiver coils and state-of-the-art MRI technology offer the user excellent image quality, **while the permanent magnet makes it easy to use and lowers operating costs**. The open magnet and the easy-to-access patient table also **facilitate, speed up and make patient positioning more comfortable**, ideal for both the claustrophobic and for children.

Esaote

The Esaote Group is a leader in the biomedical equipment sector, especially ultrasound, MRI, and medical diagnosis software. It currently has approximately 1,180 employees. With facilities in Genoa and Florence, and production and research units in Italy and the Netherlands, the company has offices in over 100 countries across the world. www.esaote.com

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