Press Release

ESAOTE completed the transition of its medical devices to the MDR-Medical Devices Regulation much ahead of the expiry of MDD-Medical Devices Directive 93/42/EEC certificates

Genoa, December 13th, 2022 – All the companies involved in the production and commercialization of medical devices have been struggling in the latest 2-3 years to achieve the migration of their products and processes from the compliance to the MDD (Medical Devices Directive 93/42/EEC) to new **MDR Regulation**.

MDR CE marking pays greater attention to technical documentation, including clinical evaluation, post-marketing clinical follow-up and traceability of devices in the supply chain, and requires a very rich documentation package, reflecting rigorous testing procedures and quality standard.

Despite the validity of the MDD CE certificates will expire in May 2024, **ESAOTE** - leading company in ultrasound, magnetic resonance and healthcare IT - has proactively started the migration process several months ago, to update the processes to the new standard, ensuring the highest level of quality in all the products' development phases and manufacturing of its medical devices.

In 2022, **ESAOTE** boasts **25 ultrasound medical devices** and **2 MRI medical devices,** all certified under the new MDR CE Mark, issued by TÜV SÜD, and by the end of 2022 **all ESAOTE ultrasound** medical devices will switch to **production under the MDR CE Mark**.

"*At Esaote, we have created a dedicated company-wide, interdepartmental project team to complete the transition of all our medical devices from the MDD to the MDR in the most efficient way*," said Franco Fontana, CEO of Esaote. "*Our Quality Management System team has driven all the actions towards this new regulation, which focuses on **quality and safety**, significantly improving the regulatory rules for medical devices to be sold in Europe.*"

Currently, in EU around 23,000 certificates are covered by the MDD CE Mark, due to expire in 2024; at present, only 4,100 are already certified under the MDR CE Mark, with an average period of about 13-18 months to obtain the first certificate (manufacturer's QMS and initial product assessment)*.

Find out more about ESAOTE Quality Management System and Certifications: https://www.esaote.com/about-esaote/innovation-technology/quality/

* Source: Official EC press release with the relevant data:
https://health.ec.europa.eu/latest-updates/notified-bodies-survey-certifications-and-applications-2022-10-26_en

About Esaote

The Esaote Group, which this year celebrates 40 years of activity, is a leader in the biomedical equipment sector, in particular in the areas of ultrasound, magnetic resonance imaging and software for managing the diagnostic process. At the end of 2021, the Group had 1,280 employees, more than half of whom were in Italy. With headquarters in Genoa and Florence and its own production and research units in Italy and the Netherlands, Esaote is present in 100 countries around the world. www.esaote.com

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