



# Certificate

No. Q5 095545 0015 Rev. 02

**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 ECG, defibrillators, patient monitoring and CT medical diagnostic devices.

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 and certification regulation of 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. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 095545 0015 Rev. 02)

**Report No.:** ITA2021698

**Valid from:** 2023-11-18

**Valid until:** 2026-11-17

**Date,** 2023-09-06

Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**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 imaging. 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 ECG, defibrillators, patient monitoring and CT medical diagnostic devices.

**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 equipment for the area of medical diagnostic imaging. Warehousing and shipping of ultrasonic probes for the area of medical diagnostic imaging.

**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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