



America

CERTIFICATE

No. QS6 095545 0016 Rev. 02

Certificate Holder:

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

Certification Mark:



Scope of Certificate:

Design and Development, Production, Installation and Servicing of Ultrasonic Diagnostic Equipment including Probes, Magnetic Resonance Diagnostic Equipment and Software for the area of Diagnostic Imaging

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 095545 0016 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:QS6_095545_0016_Rev.02)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F003004

Report No.:

ITA2021698

Effective Date:

2023-08-17

Expiry Date:

2026-08-16

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Date of Issue: 2023-08-29

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

ESAOTE S.p.A.

Via Enrico Melen 77, 16152 Genova, ITALY

ESAOTE S.p.A.

Via Multedo di Pegli 2/E, 16155 Genova, ITALY

ESAOTE S.p.A.

Via di Caciolle 15, 50127 Firenze, ITALY

ESAOTE S.p.A.

Via degli Olmi 11, 50019 Sesto Fiorentino (FI), ITALY

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Facility Scopes:

ESAOTE S.p.A.

Via Enrico Melen 77, 16152 Genova, ITALY

Design and Development of Ultrasonic Diagnostic Equipment for the area of Diagnostic Imaging; Installation and Servicing of Ultrasonic Diagnostic Equipment and Magnetic Resonance Diagnostic Equipment for the area of Diagnostic Imaging
REPs Facility ID: F003004

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 Diagnostic Imaging; Servicing of Ultrasonic Diagnostic Equipment for the area of Diagnostic Imaging
REPs Facility ID: F001666

ESAOTE S.p.A.

Via di Caciolle 15, 50127 Firenze, ITALY

Design and Development, Production of Ultrasound Probes for the area of Diagnostic Imaging
REPs Facility ID: F003005

ESAOTE S.p.A.

Via degli Olmi 11, 50019 Sesto Fiorentino (FI), ITALY

Production, Warehousing and Shipping of Ultrasonic Diagnostic Equipment Including Probes for the area of Diagnostic Imaging
REPs Facility ID: F003006



(Renee Walker)
Director, US Certification Body, MHS