



America

CERTIFICATE

No. QS6 095545 0016 Rev. 00

Certificate Holder:

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

Certification Mark:



Scope of Certificate:

**Design, 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, USA FDA,
MHLW / PMDA.
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. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

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

DUNS No:

43-738-4304

Effective Date:

2018-12-18

Expiry Date:

2021-12-17

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Date of Issue: 2018-12-29

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

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

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

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, Production, Installation and Servicing of Ultrasonic Diagnostic Equipment and Magnetic Resonance Diagnostic Equipment for the area of Diagnostic Imaging
DUNS No: 43-738-4304

ESAOTE S.p.A

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

Design of Magnetic Resonance Diagnostic Equipment and Software for the area of Diagnostic Imaging; Production of Ultrasonic Diagnostic Equipment, Magnetic Resonance Diagnostic Equipment and Software for the area of Diagnostic Imaging
DUNS No: 43-786-7173

ESAOTE S.p.A

Via di Caciolle 15, 50127 Firenze, ITALY

Design, Production, Installation and Servicing of Ultrasonic Diagnostic Equipment including Probes for the area of Diagnostic Imaging
DUNS No: 54-404-5540

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
DUNS No: 43-775-0368



(Arie Henkin)
Manager, Certification Body MHS