Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 095545 0023 Rev. 00

Manufacturer:

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

Facility(ies):

ESAOTE S.p.A.
Via degli Olmi 11, 50019 Sesto Fiorentino (FI), ITALY

ESAOTE S.p.A.
Via di Caciolle 15, 50127 Firenze, ITALY

ESAOTE S.p.A.
Via Multedo di Pegli 2/E, 16155 Genova, ITALY

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

Product Category(ies): **Ultrasonic medical diagnostic systems, Probes for ultrasonic medical diagnostic systems, Magnetic resonance imaging units for medical diagnosis, Software for diagnostic imaging**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA1290265

Valid from: 2019-06-14
Valid until: 2024-05-26

Date, 2019-06-14

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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