



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 095545 0024 Rev. 04

Manufacturer:

ESAOTE S.p.A.

Via Enrico Melen 77
16152 Genova
ITALY

SRN Manufacturer - IT-MF-000019024

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 095545 0024 Rev. 04

Report No.: ITA1951186

Preceding Certificate No.: G10 095545 0024 Rev. 03

Valid from: 2023-07-05

Valid until: 2026-08-24

Date of Initial Issuance: 2021-08-25

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-07-05



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Classification: Class IIa
Device Group: Z110401 - ULTRASOUND SCANNERS
Intended Purpose: -

Classification: Class IIa
Device Group: Z110402 - ULTRASOUND PROBES
Intended Purpose: -

Classification: Class IIa
Device Group: Z110501 - MAGNETIC RESONANCE (MR) SYSTEMS
Intended Purpose: -

Classification: Class IIa
Device Group: Z11069092 - VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose: -

The validity of this certificate /
depends on conditions and/or
is limited to the following:

Revision History:

Rev.	Dated	Report	Description
00	2021-08-25	ITA1557251	-
01	2021-11-17	ITA1685736	-
02	2022-06-02	ITA1685736_CHANGE	-
03	2022-06-10	ITA1685736_CHANGE	-
04	2023-07-05	ITA1951186	Supplemented: Device(s)/group of device(s) added