



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-099



Product Service

## 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](http://www.tuvsud.com/ps-cert?q=cert:G10 095545 0024 Rev. 04)

<b>Report No.:</b>	ITA1951186
<b>Preceding Certificate No.:</b>	G10 095545 0024 Rev. 03
<b>Valid from:</b>	2023-07-05
<b>Valid until:</b>	2026-08-24
<b>Date of Initial Issuance:</b>	2021-08-25

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2023-07-05



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KOPIJA TIKRA  
Direktorius  
Algis Bėkūnas  
2024-07-08



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## EU Quality Management System Certificate (MDR)

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

**No. G10 095545 0024 Rev. 04**

**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

# DICHIARAZIONE DI CONFORMITÀ UE EU DECLARATION OF CONFORMITY

Noi costruttori / We manufacturer

**Esaote S.p.A.**

Via Enrico Melen 77, 16152 Genova - ITALIA  
SRN - IT-MF-000019024



dichiaro, sotto la nostra esclusiva responsabilità, che il dispositivo per diagnostica ad ultrasuoni  
*declare, under our sole responsibility, that the ultrasound medical device*

## Serie 6450 Modello MyLabX8 Series 6450 Model MyLabX8

Destinazione d'uso: Il dispositivo multifunzionale ad ultrasuoni viene utilizzato per raccogliere, visualizzare ed analizzare le immagini ad ultrasuoni durante le procedure di acquisizione di immagini in combinazione con le sonde ecografiche supportate.

*Intended purpose: The multifunctional ultrasound device is used to collect, display, and analyse ultrasound images during ultrasound imaging procedures in combination with supported echographic probes.*

è stato progettato e costruito in conformità:

- al Regolamento (UE) 2017/745 del Parlamento Europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medici (MDR) e sue successive modifiche
- alla Direttiva 2011/65/EU del Parlamento Europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche (RoHS) e sue successive modifiche
- ai Requisiti Essenziali dell'articolo III della Direttiva 2014/53/EU del Parlamento Europeo e del Consiglio del 16 aprile 2014 concernente l'armonizzazione delle legislazioni degli Stati membri relative alla messa a disposizione sul mercato di apparecchiature radio (RED)

*has been developed and manufactured in compliance with:*

- *the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) and its successive amendments*
- *the Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), and its successive amendments*
- *the Essential Requirements stated by article 3 of the Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (RED)*

### MDR

Classe di rischio secondo l'Allegato VIII del Regolamento 2017/745: <i>Risk class according to Annex VIII of the Regulation 2017/745:</i>	IIa
UDI-DI di base: <i>Basic UDI-DI:</i>	805630445ESA.US0000004.Y4
Codice EMDN: <i>EMDN Code:</i>	Z110401
Numero identificativo dell'Organismo Notificato: <i>Notified Body identification number:</i>	0123
Nome e indirizzo dell'Organismo Notificato: <i>Notified Body name and address:</i>	TÜV Süd Product Service GmbH, Ridlerstr.65, D-80339 Munich - DE
Valutazione della conformità:  <i>Conformity assessment:</i>	basata sull'Allegato IX del MDR escluso il capitolo II <i>based on Annex IX of the MDR excluding chapter II</i>
Prima data di emissione: <i>Issued for the first time:</i>	2022-10-04

Numero del Certificato CE:

EC Certificate Number:

Valido fino a:

Valid until:

2024-07-08

KOPĖJA IKRA  
Direktorius  
Algis Bakutis



La conformità alle disposizioni delle Direttive applicate è dimostrata dalla conformità alle seguenti norme  
The conformity with the provisions of the applied Directive(s) is demonstrated by compliance with the following standards

### RoHS

Nr. e Edizione/Nr. and Edition	Titolo/Title
EN IEC 63000:2018-12	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

### RED

Risponde ai Requisiti Essenziali della direttiva 2014/53/UE – RED controllo interno della produzione come previsto dall'Allegato II

Meets the Essential Requirements of the 2014/53/EU directive – RED internal production control as set out in Annex II

Nr. e Edizione/Nr. and Edition	Titolo/Title
EN 60601-1:2006 + A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015/A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: ElectroMagnetic Compatibility - Requirements and tests
EN 60601-1-6:2010+A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-2-37:2008	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN 62311:2008	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
ETSI EN 301 489-1 v2.2.3	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
ETSI EN 301 489-17 v3.2.4	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility
ETSI EN 300 328 v2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
ETSI EN 301 893 V2.1.1	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Luogo e data:

Place and date:

Genova - ITALIA 2022-10-04

  
Ing. Massimo Polignano

Responsabile Assicurazione Qualità  
Chief Quality Officer