



Product Service

Certificate

No. Q5 095545 0015 Rev. 00

Holder of Certificate: **ESAOTE S.p.A.**
Via Enrico Melen 77
16152 Genova
ITALY

Certification Mark:



Scope of Certificate: Design and development, production, sales, installation, put into service and servicing of medical and software systems for diagnosis and therapy aid in the following human applications: MRI, ultrasound, management of medical data and images. Design, sales, distribution, installation, start - up and services of hardware systems, software, IT networks for the management of data and images in medical and healthcare environment. Sales, installation, put into service and servicing of medical and software systems for diagnosis in the following human applications: ECG, defibrillators and patient monitoring. Servicing of CT medical diagnostic devices

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA11251281SAC

Valid from: 2018-10-17

Valid until: 2020-11-17

Date, 2018-10-17

Stefan Preiß

Certificate

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

ESAOTE EUROPE B.V.
Philipsweg 1, 6227 AJ Maastricht, THE NETHERLANDS

EBIT S.r.l.
Via Enrico Melen 77, 16152 Genova, ITALY

SHENZHEN ESAOTE MEDICAL TECHNOLOGY Co. Ltd
No. 703, 7th Floor, Factory Building 1 of Technology Park
(FuLiZhen Building), No.1 Kefa RD, Nanshan District, 518057
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

EBIT S.r.l.
Via di Caciolle 15, 50127 Firenze, ITALY

PROTON B.V.
Dr. Nolenslaan 157-j, 6136 GM Sittard, THE NETHERLANDS

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

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

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

ESAOTE NORTH AMERICA Inc
11907 Exit Five Parkway, Fishers IN 46037, USA

Certificate

No. Q5 095545 0015 Rev. 00

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

Design and development, production, sales, installation, put into service and servicing of medical and software systems for diagnosis and therapy aid in the following human applications: MRI, ultrasound, management of medical data and images. Sales, installation, put into service and servicing of medical and software systems for diagnosis in the following human applications: ECG, defibrillators and patient monitoring. Servicing of CT medical diagnostic devices

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

Design and development, production, sales, installation, put into service and servicing of medical and software systems for diagnosis and therapy aid in the following human applications: MRI, ultrasound, management of medical data and images.

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

Design and development, production, sales, installation, put into service and servicing of medical and software systems for diagnosis and therapy aid in the following human applications: ultrasound, management of medical data and images. Design, development, sales, installation, put into service and servicing of medical and software systems for diagnosis and therapy aid in the following human applications: MRI. Sales, installation, put into service and servicing of medical and software systems for diagnosis in the following human applications: ECG, defibrillators and patient monitoring.

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

Production, warehouse and shipping of medical systems for diagnosis in the following human applications: ultrasonic devices, management of medical and data images

EBIT S.r.l., Via Enrico Melen 77, 16152 Genova, ITALY

Design and development, production, sales, distribution, installation and service of software systems for the management of data and images in medical and healthcare environment. Sales, distribution, installation and service of hardware medical diagnostic systems for the management of data and images in medical and healthcare environment.

EBIT S.r.l., Via di Caciolle 15, 50127 Firenze, ITALY

Sales, distribution, installation, and service of software systems for the management of data and images in medical and healthcare environment. Sales, distribution, installation and service of hardware medical diagnostic systems for the management of data and images in medical and healthcare environment.

SHENZHEN ESAOTE MEDICAL TECHNOLOGY Co. Ltd, No. 703, 7th Floor, Factory Building 1 of Technology Park (FuLiZhen Building), No.1 Kefa RD, Nanshan District, 518057 Shenzhen, CHINA:

Design and development, production of medical and software systems for diagnosis and therapy aid in the following human applications: ultrasound, management of medical data and images

ESAOTE NORTH AMERICA Inc, 11907 Exit Five Parkway, Fishers IN 46037, USA

Distribution, installation and servicing of diagnostic ultrasound equipment, magnetic resonance imaging systems and related accessories

PROTON B.V., Dr. Nolenslaan 157-j, 6136 GM Sittard, THE NETHERLANDS

Production and servicing of medical ultrasonic diagnostic transducers, probes and devices.

ESAOTE EUROPE B.V., Philipsweg 1, 6227 AJ Maastricht, THE NETHERLANDS

Design and development, sales, installation, put into service and servicing of medical systems for diagnosis in the following human applications: ultrasonic devices, management of medical and data images