



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 022775 0009 Rev. 01

Manufacturer:

**Siemens Medical Solutions USA,
Inc.**

22010 S.E. 51st Street
Issaquah, WA 98029
USA

Product Category(ies): Diagnostic Ultrasound Imaging Systems,
Ultrasound Transducer,
Cardiac Ultrasound Transducers and
related Software for medical workplaces

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. 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:G10227750009Rev.01

Report No.: 713198855

Valid from: 2021-03-22

Valid until: 2024-05-26

Date, 2021-03-22

Christoph Dicks
Head of Certification/Notified Body



Product Service

Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 022775 0016 Rev. 00**Manufacturer:****Siemens Medical Solutions USA,
Inc.**22010 S.E. 51st Street
Issaquah, WA 98029
USA**This List of Sites is only
valid in combination with the
following EC Certificate (MDD):****G1 022775 0009 Rev. 01**

The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EC Certificate pursuant to the Directive 93/42/EEC (MDD) concerning medical devices.

Report No.:

713198855

Valid until:

2024-05-26

Issue Date: 2021-03-26(Lars Pinger)
PS-MHS-FA-0 – Foreign Affairs

**Confirmation Statement related to the EC Certificate (MDD)**

List of Sites involved in the Product Realisation Processes

No. GDS 022775 0016 Rev. 00**Sites:**

Siemens Medical Solutions USA, Inc.
5168 Campus Drive, Plymouth Meeting PA 19462, USA

Siemens Healthineers Ltd.
KINS TOWER, 8, Seongnam-daero 331beon-gil, Bundang-gu,
Seongnam-si, Gyeonggi-Do, REPUBLIC OF KOREA

Siemens Healthineers Ltd.
2nd ~ 3rd Floor, 143, Sunhwan-ro, Jungwon-gu, Seongnam-Si,
Gyeonggi-Do, REPUBLIC OF KOREA

Siemens Medical Solutions USA, Inc.
22010 S.E. 51st Street, Issaquah, WA 98029, USA

Siemens Healthineers Ltd.
2nd & 3rd Venture Building, Pohang Technopark, 394, Jigok-ro,
Nam-gu, Pohang-si, Gyeongsangbuk-Do, REPUBLIC OF KOREA