





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:G1 022775 0009 Rev. 01

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Valid from: 2021-03-22 Valid until: 2024-05-26

Date, 2021-03-22

Christoph Dicks

Head of Certification/Notified Body