



Product Service

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 16 01 91596 004

Manufacturer:

Siemens Healthcare GmbH

Henkestr. 127
91052 Erlangen
GERMANY



Product Category(ies):

**Imaging Systems, Therapy Systems and
Robotic Surgical Navigation Systems and
related Hardware and Software
(for detailed information see attachment)**

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. See also notes overleaf.

Report No.:

713075520

Valid from:

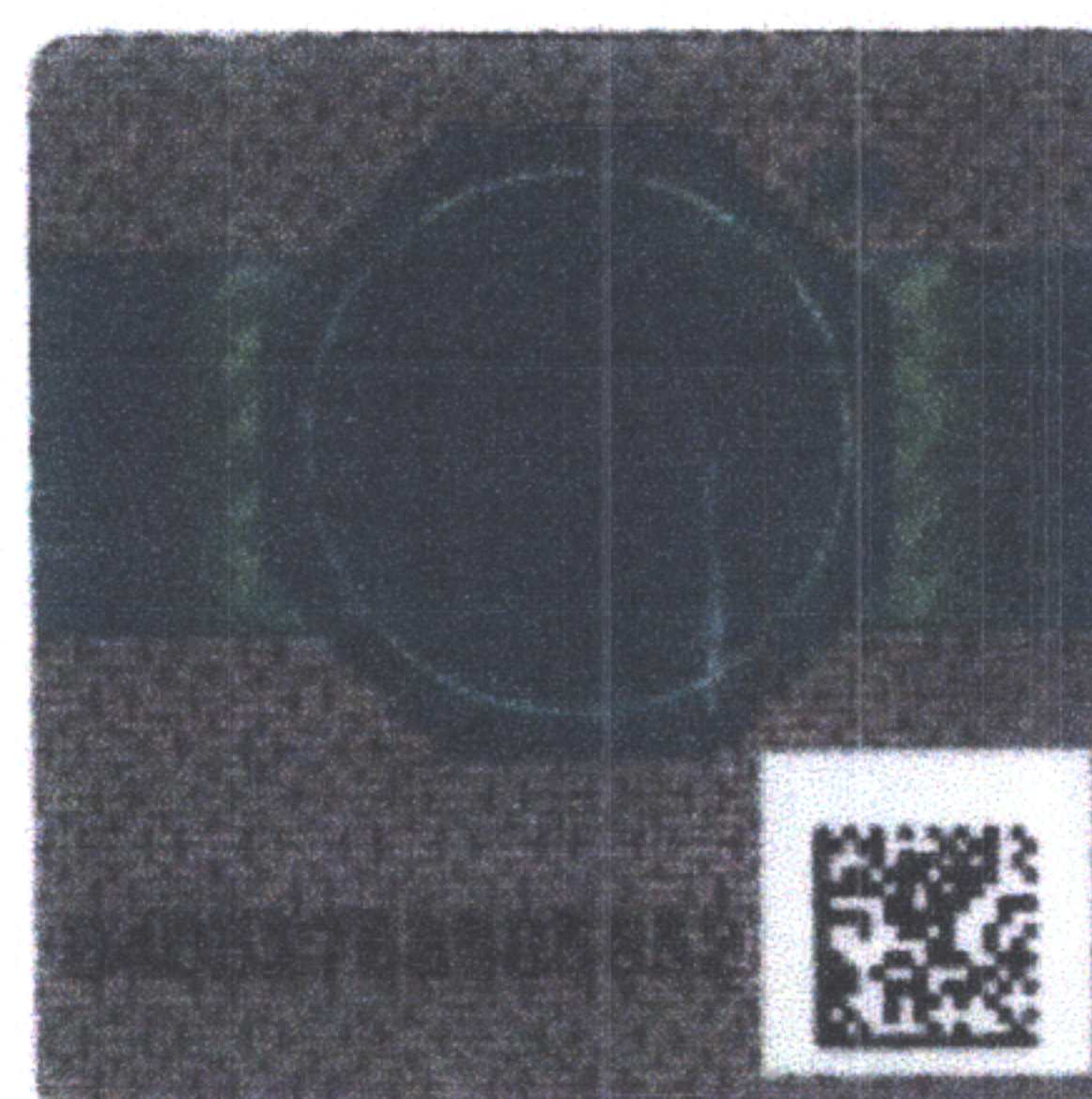
2016-04-26

Valid until:

2021-04-25

Date, 2016-02-26

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

**Attachment for Certificate no G1 16 01 91596 004
valid from 2016-04-26**

Supplement 001 dated 2016-02-26 (713075520)

Facility(ies):

Siemens Healthcare GmbH
Advanced Therapies
Siemensstr. 1, 91301 Forchheim, Germany
Siemens Medical Solutions USA, Inc.
2501 North Barrington Road, Hoffman Estates IL 60195, USA
Angiography-, Fluoroscopic-, Radiographic-Systems and
Hemodynamic / Electrophysiology Recording and Information Systems,
Medical Workplaces, Related Software

Siemens Healthcare GmbH
Components and Vacuum Technology (CV)
Henkestr. 127, 91052 Erlangen, Germany
Guenther-Scharowsky-Str. 21, 91058 Erlangen, Germany
Roentgenstr. 2, 07407 Rudolstadt, Germany
Roentgenstr. 19 - 21, 95478 Kemnath, Germany
Siemens Shanghai Medical Equipment Ltd., Unit CV
278 Zhouzhu Road, 201318 Shanghai, P.R. China
Siemens X-Ray Vacuum Technology Ltd., Wuxi
No. 112, Meiyu Road, 214028 Wuxi, Jiangsu, P.R. China
Siemens Shenzhen Magnetic Resonance Ltd., Unit CV
Gaoxin C. Ave. 2nd, Hi-Tech Industrial Park, 518057 Shenzhen, P.R. China
X-ray Tube Housing Assemblies, X-Ray Generators, Collimators, Radiographic /
Fluoroscopic Systems, X-Ray / Tomographic Examination Devices, related Software

Siemens Healthcare GmbH
SYNGO (SY)
Henkestr. 127, 91052 Erlangen, Germany
Siemens Medical Solutions USA, Inc.,
20 Valley Stream Parkway, Malvern PA 19355, USA
Siemens Medical Solutions USA, Inc.
400 W. Morgan Road, Ann Arbor MI 48108, USA
Advanced Visualization Software, Imaging and Clinical Software Products, Picture Archiving and
Communication Systems (PACS) - Software Components and Systems, Workplaces and Medical
Workstations

Siemens Healthcare GmbH
Magnetic Resonance (MR)
Henkestr. 127, 91052 Erlangen, Germany
Magnetic Resonance Devices and hybrid Magnetic Resonance
and Molecular Imaging Devices including the Applicable Software



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**Attachment for Certificate no G1 16 01 91596 004
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Product Service

Supplement 001 dated 2016-02-26 (713075520)

Facility(ies):

Siemens Healthcare GmbH
X-Ray Products (XP)
Henkestr. 127, 91052 Erlangen, Germany
Siemensstr. 1, 91301 Forchheim, Germany
Roentgenstr. 19 – 21, 95478 Kemnath, Germany
X-Ray Systems, Systems of extra corporeally induced
Lithotripsy / Therapy, Workplaces, Accessories, related Software;
Robotic Surgical Navigation Systems and associated Application
Software, Surgical Planning Software with Measuring Function

Siemens Healthcare GmbH
Computed Tomography (CT)
Siemensstr. 1, 91301 Forchheim, Germany
Computed Tomography, Medical Components and Systems,
Medical Workplaces and Software

Siemens Healthcare GmbH
Advanced Therapies, Radiation Oncology
Doris-Ruppenstein-Str. 4, 91052 Erlangen, Germany
Roentgenstr. 19-21, 95478 Kemnath, Germany
Linear Accelerators, Collimators, Planning Software and Radiotherapy Simulators

Siemens Healthcare GmbH,
Advanced Therapies, Particle Therapy
Hofmannstr. 26, 91052 Erlangen, Germany
Particle Therapy Systems and Related Software

München, CRT2, 2016-02-26

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