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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



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 091596 0025 Rev. 01

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**

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.:

713141729

Valid from:

2018-10-01

Valid until:

2023-09-30

Date,

2018-09-25

Stefan Preiß



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Facility(ies):

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Henkestr. 127, 91052 Erlangen, GERMANY

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Siemens Healthcare GmbH, Computed Tomography (CT)
Siemensstr. 1, 91301 Forchheim, GERMANY

Siemens Healthcare GmbH, Advanced Therapies
Siemensstr. 1, 91301 Forchheim, GERMANY

Siemens Healthcare GmbH, Magnetic Resonance (MR)
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Siemens Healthcare GmbH Advanced Therapies, Particle Therapy
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PEOPLE'S REPUBLIC OF CHINA

Siemens Healthcare GmbH Advanced Therapies, Radiation
Oncology
Doris-Ruppenstein-Str. 4, 91052 Erlangen, GERMANY

Siemens Healthcare GmbH, X-Ray Products (XP)
Siemensstr. 1, 91301 Forchheim, GERMANY

Siemens Healthcare GmbH Advanced Therapies, Radiation
Oncology
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2501 North Barrington Road, Hoffman Estates IL 60192, USA
Angiography-, Fluoroscopic-, Radiographic-Systems and
Hemodynamic / Electrophysiology Recording and Information Systems,
Medical Workplaces, Related Software

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Siemens Shenzhen Magnetic Resonance Ltd., Unit TC

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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)

Siemensstr. 1, 91301 Forchheim, Germany

Henkestr. 127, 91052 Erlangen, Germany

Siemens Medical Solutions USA, Inc., SYNGO

400 W. Morgan Road, Ann Arbor MI 48108, USA

Siemens Medical Solutions USA, Inc., SYNGO

65 Valley Stream Parkway, Malvern PA 19355, 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

Digital Services (DS)

Henkestr. 127, 91052 Erlangen, Germany

Siemens Medical Solutions USA, Inc., Digital Services

65 Valley Stream Parkway, Malvern PA 19355, USA

Advanced Visualization Software, Imaging and Clinical Software Products and
Software Components

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

Siemens Healthcare GmbH

X-Ray Products (XP)

Siemensstr. 1, 91301 Forchheim, 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

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Particle Therapy Systems and Related Software