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www.zfg.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):

Siemens Healthcare GmbH SYNGO (SY)
Henkestr. 127, 91052 Erlangen, GERMANY

Siemens Healthcare GmbH Technology Centers (TC)
Rittigfeld 1, 91301 Forchheim, GERMANY

Siemens Medical Solutions USA, Inc. SYNGO
65 Valley Stream Parkway, Malvern PA 19355, USA

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)
Henkestr. 127, 91052 Erlangen, GERMANY

Siemens Healthcare GmbH Technology Centers (TC)
Henkestr. 127, 91052 Erlangen, GERMANY

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Röntgenstr. 19-21, 95478 Kemnath, GERMANY

Siemens Healthcare GmbH Technology Centers (TC)
Günther-Scharowsky-Str. 21, 91058 Erlangen, GERMANY

Siemens Healthcare GmbH Technology Centers (TC)
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Siemens Healthcare GmbH Digital Services (DS)
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Siemens Medical Solutions USA, Inc.
2501 North Barrington Road, Hoffman Estates IL 60192, USA

Siemens Medical Solutions USA, Inc. SYNGO
400 W. Morgan Road, Ann Arbor MI 48108, USA

Siemens Medical Solutions USA, Inc. Digital Services
65 Valley Stream Parkway, Malvern PA 19355, USA

Siemens Healthcare GmbH Advanced Therapies, Particle Therapy
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CHINA

Siemens Shenzhen Magnetic Resonance, Ltd Unit TC
Hi-Tech Industrial Park, Gaoxin C. Ave., 2nd., 518057 Shenzhen,

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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
Röntgenstr. 19 21, 95478 Kemnath, GERMANY

Siemens X-Ray Vacuum Technology Ltd.
No.112, Meiyu Road, 214028 Wuxi, Jiangsu, PEOPLE'S
REPUBLIC OF CHINA

Siemens Healthcare GmbH Technology Centers (TC)
Siemensstr. 1, 91301 Forchheim, GERMANY

Siemens Healthcare GmbH Advanced Therapies
Röntgenstr. 19 - 21, 95478 Kemnath, GERMANY

Siemens Healthcare GmbH SYNGO (SY)
Siemensstr. 1, 91301 Forchheim, GERMANY

Siemens Healthcare GmbH
Advanced Therapies
Siemensstr. 1, 91301 Forchheim, Germany
Roentgenstr. 19 - 21, 95478 Kemnath, Germany
Siemens Medical Solutions USA, Inc.
2501 North Barrington Road, Hoffman Estates IL 60192, USA
Angiography-, Fluoroscopic-, Radiographic-Systems and
Hemodynamic / Electrophysiology Recording and Information Systems,
Medical Workplaces, Related Software

Siemens Healthcare GmbH
Technology Centers (TC)
Henkestr. 127, 91052 Erlangen, Germany
Guenther-Scharowsky-Str. 21, 91058 Erlangen, Germany
Siemensstr. 1, 91301 Forchheim, Germany
Rittigfeld 1, 91301 Forchheim., Germany
Roentgenstr. 2, 07407 Rudolstadt, Germany
Roentgenstr. 19 - 21, 95478 Kemnath, Germany
Siemens Shanghai Medical Equipment Ltd., Unit TC
278 Zhouzhu Road, 201318 Shanghai, P.R. China
Siemens X-Ray Vacuum Technology Ltd.
No. 112, Meiyu Road, 214028 Wuxi, Jiangsu, P.R. China
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

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Siemens Medical Solutions USA, Inc., Digital Services
65 Valley Stream Parkway, Malvern PA 19355, USA
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Software Components

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and Molecular Imaging Devices including the Applicable Software

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Lithotripsy / Therapy, Workplaces, Accessories, related Software;
Robotic Surgical Navigation Systems and associated Application
Software, Surgical Planning Software with Measuring Function

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

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