



# Certificate

No. Q5 091596 0026 Rev. 06

**Holder of Certificate:** **Siemens Healthcare GmbH**  
Henkestr. 127  
91052 Erlangen  
GERMANY

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production, Distribution, Installation, Putting in Operation, Maintenance and Refurbishing of:**

- Imaging- and Therapy Systems and Related Hardware and Software;
- Radiation Therapy Products and Radiation Therapy Software for Oncology Care Systems;
- Hardware and Software for Computer Assisted Surgery and Radiology;

**Production and Distribution of In-Vitro-Diagnostic Instruments**

**Customer Service and Customer Training in Germany**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 091596 0026 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:Q5 091596 0026 Rev. 06)

**Report No.:** 713200048

**Valid from:** 2021-05-15

**Valid until:** 2022-02-15

**Date,** 2021-05-12

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

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## Applied Standard(s):

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

## Facility(ies):

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

Design and Development, Production, Distribution and  
Refurbishing of Angiography-, Fluoroscopic-, Radiographic  
Systems, Hemodynamic/Electrophysiology Recording and  
Information Systems, Medical Workplaces, Related Software

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

Design and Development, Production, Distribution and  
Refurbishing of Angiography-, Fluoroscopic-, Radiographic  
Systems, Hemodynamic/Electrophysiology Recording and  
Information Systems, Medical Workplaces, Related Software

Siemens Healthcare, S.L.  
Avenida Leonardo da Vinci 15, 28906 Getafe (Madrid), SPAIN

Design and Development, Production, Distribution and  
Refurbishing of Angiography-, Fluoroscopic-, Radiographic  
Systems, Hemodynamic/Electrophysiology Recording and  
Information Systems, Medical Workplaces, Related Software

Siemens Healthcare Private Limited Unit AT  
GOLD HILL SUPREME SOFTWARE PARK II, Plot No - 21, 22, 27  
& 28, EAST TOWER, ELECTRONIC CITY PHASE- 2, Bangalore  
560100, INDIA

Design and Development, Production of Angiography-,  
Fluoroscopic-, Radiographic-Systems,  
Hemodynamic/Electrophysiology Recording and Information  
Systems, Medical Workplaces, Related Software

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

Design and Development, Production and Servicing of Radiation  
Therapy Products and Radiation Therapy Software for Oncology  
Care Systems

Siemens Healthcare GmbH, Radiation Oncology  
Röntgenstr. 19 21, 95478 Kemnath, GERMANY

Design and Development, Production and Servicing of Radiation  
Therapy Products and Radiation Therapy Software for Oncology  
Care Systems

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Siemens Healthcare GmbH, Particle Therapy  
Hofmannstr. 26, 91052 Erlangen, GERMANY

Design and Development, Production, Distribution, Installation,  
Refurbishing and Putting into Operation of Components of Particle  
Therapy Systems including the Applicable Software

Siemens Healthcare GmbH Technology Excellence (TE)  
Henkestr. 127, 91052 Erlangen, GERMANY

Design and Development, Production and Distribution of In-Vitro-  
Diagnostic Instruments, X-ray Tube  
Housing Assemblies, Image Intensifiers, Assemblies,  
Components, Sub-Systems, Systems for Diagnostic and  
Therapeutic Medical Devices including the Applicable Software

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

Design and Development, Production and Distribution of In-Vitro-  
Diagnostic Instruments, X-ray Tube  
Housing Assemblies, Image Intensifiers, Assemblies,  
Components, Sub-Systems, Systems for Diagnostic and  
Therapeutic Medical Devices including the Applicable Software

Siemens Healthcare GmbH, Technology Excellence (TE)  
Röntgenstr. 2, 07407 Rudolstadt, GERMANY

Design and Development, Production and Distribution of In-Vitro-  
Diagnostic Instruments, X-ray Tube  
Housing Assemblies, Image Intensifiers, Assemblies,  
Components, Sub-Systems, Systems for Diagnostic and  
Therapeutic Medical Devices including the Applicable Software

Siemens Healthcare GmbH, Technology Excellence (TE)  
Röntgenstr. 19-21, 95478 Kemnath, GERMANY

Design and Development, Production and Distribution of In-Vitro-  
Diagnostic Instruments, X-ray Tube  
Housing Assemblies, Image Intensifiers, Assemblies,  
Components, Sub-Systems, Systems for Diagnostic and  
Therapeutic Medical Devices including the Applicable Software

Siemens Healthcare GmbH, Technology Excellence (TE)  
Siemensstr. 1, 91301 Forchheim, GERMANY

Design and Development, Production and Distribution of In-Vitro-  
Diagnostic Instruments, X-ray Tube  
Housing Assemblies, Image Intensifiers, Assemblies,  
Components, Sub-Systems, Systems for Diagnostic and  
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# Certificate

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Siemens Healthcare GmbH, Technology Excellence (TE)  
Rittigfeld 1, 91301 Forchheim, GERMANY

Design and Development, Production and Distribution of  
Assemblies, Components, Sub-Systems, Systems for Diagnostic  
and Therapeutic Medical Devices including the Applicable  
Software

Siemens Shanghai Medical Equipment Ltd., Unit TC  
278 Zhou Zhu Road, 201318 Shanghai, PEOPLE'S REPUBLIC OF  
CHINA

Design and Development, Production and Distribution of In-Vitro-  
Diagnostic Instruments, X-ray Tube  
Housing Assemblies, Image Intensifiers, Assemblies,  
Components, Sub-Systems, Systems for Diagnostic and  
Therapeutic Medical Devices including the Applicable Software

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

Design and Development, Production and Distribution of In-Vitro-  
Diagnostic Instruments, X-ray Tube  
Housing Assemblies, Image Intensifiers, Assemblies,  
Components, Sub-Systems, Systems for Diagnostic and  
Therapeutic Medical Devices including the Applicable Software

Siemens Shenzhen Magnetic Resonance, Ltd Unit TC  
Hi-Tech Industrial Park, Gaoxin C. Ave., 2nd., 518057 Shenzhen,  
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of In-Vitro-  
Diagnostic Instruments, X-ray Tube  
Housing Assemblies, Image Intensifiers, Assemblies,  
Components, Sub-Systems, Systems for Diagnostic and  
Therapeutic Medical Devices including the Applicable Software

Siemens Shenzhen Magnetic Resonance Ltd. Unit TC  
Hong Fa Yuan Tang Tou Logistics Park, 1st building, Zhou Si  
Road Bao' An District, 518108 Shenzhen, PEOPLE'S REPUBLIC  
OF CHINA

Design and Development, Production and Distribution of In-Vitro-  
Diagnostic Instruments, X-ray Tube  
Housing Assemblies, Image Intensifiers, Assemblies,  
Components, Sub-Systems, Systems for Diagnostic and  
Therapeutic Medical Devices including the Applicable Software

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

# Certificate

No. Q5 091596 0026 Rev. 06

Design and Development, Production, Distribution and Refurbishing of Computed Tomography, Medical Components and Systems, Medical Workplaces and Software

Siemens Healthcare GmbH, Magnetic Resonance (MR)  
Henkestr. 127, 91052 Erlangen, GERMANY

Design and Development, Production, Distribution and Refurbishing of Systems and Components for Magnetic Resonance Devices and hybrid Magnetic Resonance and Molecular Imaging Devices including the Applicable Software

Siemens Healthcare GmbH, Digital Health (DH)  
Henkestr. 127, 91052 Erlangen, GERMANY

Design and Development, Production, Distribution, Installation and Support of Advanced Visualization Software, Imaging and Clinical Software Products and Software Components

Siemens Healthcare Limited Digital Health (DH)  
508 Riverbend Drive, Kitchener ON N2K 3S2, CANADA

Design and Development, Production, Distribution, Installation and Support of Advanced Visualization Software, Imaging and Clinical Software Products and Software Components

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

Design and Development, Production, Distribution, Installation and Support of Advanced Visualization Software, Imaging and Clinical Software Products, Picture Archiving and Communication Systems (PACS) - Software Components and Systems, Workplaces and Medical Workstations

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

Design and Development, Production, Distribution, Installation and Support of Advanced Visualization Software, Imaging and Clinical Software Products, Picture Archiving and Communication Systems (PACS) - Software Components and Systems, Workplaces and Medical Workstations

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

Design and Development, Production, Distribution, Installation and Support of Advanced Visualization Software, Imaging and Clinical Software Products, Picture

# Certificate

No. Q5 091596 0026 Rev. 06

Archiving and Communication Systems  
(PACS) - Software Components and Systems, Workplaces and  
Medical Workstations

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

Design and Development, Production, Distribution and  
Refurbishing of X-Ray Systems, Systems of extra corporeally  
induced Lithotripsy / Therapy, Workplaces, Accessories, Related  
Software, Hardware and Software for Computer Assisted Surgery  
and Radiology; Merchandise

Siemens Healthcare GmbH Customer Services  
Henkestr. 127, 91052 Erlangen, GERMANY

Customer Services for Medical Devices and related Hardware and  
Software