



Product Service

Certificate

No. Q5 091596 0026 Rev. 09

Holder of Certificate: **Siemens Healthcare GmbH**

Henkestr. 127
91052 Erlangen
GERMANY

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution, Installation and Servicing of:**

- Imaging Systems utilizing Ionizing Radiation and Magnetic Resonance Techniques and Related Hardware, Accessories and Software;
- Devices for Recording and Information of Vital Physiological Parameters;
- Hardware and Software for Computer Assisted Surgery and Radiology;
- Software for Radiation Therapy for Oncology Care and Accessories for Treatment Support and Planning;
- Picture Archiving and Communication Systems (PACS), Advanced Visualization Software and Software Components;

The Provision of Production and Distribution Services of In-Vitro-Diagnostic Instruments

The Provision of Production, Assembly, Packaging and Distribution Services of Components of Radiation Therapy Systems

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, Certification, Validation and Verification Regulations 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. 09](http://www.tuvsud.com/ps-cert?q=cert:Q5_091596_0026_Rev_09)

Report No.: 713310862

Valid from: 2024-05-15
Valid until: 2027-05-14

Date, 2024-05-14

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 091596 0026 Rev. 09

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Siemens Healthcare GmbH**
Henkestr. 127, 91052 Erlangen, GERMANY

Legal Manufacturer
Management, Regulatory Affairs, Audits of internal Suppliers

Siemens Healthineers AG, Advanced Therapies
Siemensstr. 1, 91301 Forchheim, GERMANY

Design and Development, Production, Distribution, Installation and
Refurbishing of Imaging Systems utilizing Ionizing Radiation
(Angiography-, Fluoroscopic-, Radiographic-Systems), Devices for
Recording and Information of Vital Physiological Parameters, and
related Medical Workplaces and Software

Siemens Healthineers AG, Advanced Therapies
Röntgenstr. 19 - 21, 95478 Kemnath, GERMANY

Production of Imaging Systems utilizing Ionizing Radiation
(Angiography-, Fluoroscopic-, Radiographic-Systems)

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

Design and Development of Software for Imaging Systems utilizing
Ionizing Radiation (Angiography-, Fluoroscopic-, Radiographic-
Systems), Devices for Recording and Information of Vital
Physiological Parameters and related Medical Workplaces

Siemens Healthcare, S.L.
Edificio Mezquitas Plaza, Calle Francisco Gasco Santillán n° 2,
Planta Baja, Local 3B, 28906 Getafe (Madrid), SPAIN

Design and Development of Software for Imaging Systems utilizing
Ionizing Radiation (Angiography-, Fluoroscopic-, Radiographic-
Systems)

Certificate

No. Q5 091596 0026 Rev. 09

Facility(ies):

Siemens Healthineers AG, Computed Tomography (CT)

Siemensstr. 1, 91301 Forchheim, GERMANY

Design and Development, Production, Distribution, Installation and Refurbishing of Imaging Systems utilizing Ionizing Radiation (Computed Tomography) and related Medical Components, Medical Workplaces and Software

Siemens Healthineers AG, Computed Tomography (CT)

Rittigfeld 1, Halle E, 91301 Forchheim, GERMANY

Production, Distribution and Refurbishing of Imaging Systems utilizing Ionizing Radiation (Computed Tomography) and related Medical Components

Siemens Healthineers AG, Business Line CTH (Cancer Therapy)

Doris-Ruppenstein-Str. 4, 91052 Erlangen, GERMANY

Design, Development and Distribution of Software Applications for Digital Imaging Systems and Accessories for Treatment Support and Planning

Siemens Healthineers AG, Digital & Automation (D&A)

Siemensstr. 1, 91301 Forchheim, GERMANY

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

Siemens Healthineers AG, Digital & Automation (D&A)

Henkestr. 127, 91052 Erlangen, GERMANY

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

Certificate

No. Q5 091596 0026 Rev. 09

Facility(ies):

Siemens Medical Solutions USA, Inc. Digital & Automation (D&A)

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

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

Siemens Healthineers AG, Particle Therapy

Hofmann Str. 26, 91052 Erlangen, GERMANY

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

Siemens Healthineers AG, Magnetic Resonance (MR)

Allee am Röthelheimpark 2, 91052 Erlangen, GERMANY

Design and Development, Production, Distribution, Installation and Refurbishing of Imaging Systems utilizing Magnetic Resonance Techniques (Magnetic Resonance Devices and hybrid Magnetic Resonance and Molecular Imaging Devices) and related Medical Components, Medical Workplaces, Accessories and Software

Siemens Healthineers AG, Magnetic Resonance (MR)

Henkestr. 127, 91052 Erlangen, GERMANY

Design and Development, Production, Distribution, Installation and Refurbishing of Imaging Systems utilizing Magnetic Resonance Techniques (Magnetic Resonance Devices and hybrid Magnetic Resonance and Molecular Imaging Devices) and Related Medical Components, Medical Workplaces, Accessories and Software

Siemens Healthineers AG, Magnetic Resonance (MR)

Hartmannstr. 16, 91052 Erlangen, GERMANY

Production and Refurbishing of Components for Imaging Systems utilizing Magnetic Resonance Techniques (Magnetic Resonance Devices and hybrid Magnetic Resonance and Molecular Imaging Devices)

Certificate

No. Q5 091596 0026 Rev. 09

Facility(ies):

Siemens Healthineers AG, Technology Excellence (TE)

Allee am Röthelheimpark 2, 91052 Erlangen, GERMANY

The Provision of Design and Development, Production, Assembly, Packaging and Distribution Services for Components for Medical Imaging Devices (PCB Assemblies, Assemblies, Computers and Grids)

Siemens Healthineers AG, Technology Excellence (TE)

Henkestr. 127, 91052 Erlangen, GERMANY

Design and Development, Production, Assembly, Packaging and Distribution of Components of Medical Imaging Devices (X-Ray Tube Assemblies)

Siemens Healthineers AG, Technology Excellence (TE)

Günther-Scharowsky-Str. 21, 91058 Erlangen, GERMANY

Design and Development, Production, Assembly, Packaging and Distribution of Components for Medical Imaging Devices (X-Ray Tube Assemblies)

Siemens Healthineers AG, Technology Excellence (TE)

Henri-Dunant-Str. 50, 91058 Erlangen, GERMANY

The Provision of Design and Development Services for Components of Medical Imaging Devices (PCB Assemblies, Assemblies and Computers)

Siemens Healthineers AG, Technology Excellence (TE)

An der Lände 9, 91301 Forchheim, GERMANY

Design and Development, Production, Assembly, Packaging and Distribution for Components of Medical Imaging Devices (high voltage Generators and X-ray Tube Assemblies)

Certificate

No. Q5 091596 0026 Rev. 09

Facility(ies):

Siemens Healthineers AG, Technology Excellence (TE)

An den Sandgruben 1, 91301 Forchheim, GERMANY

The Provision of Reuse, Packaging and Distribution Services for Component of Medical Imaging Devices (X-Ray Tube Assemblies)

Siemens Healthineers AG, Technology Excellence (TE)

Simon-Hegele-Str. 1, 91301 Forchheim, GERMANY

The Provision of Repair, Packaging and Distribution Services for Components of Medical Imaging Devices (PCB Assemblies, Assemblies and Computers)

Siemens Healthineers AG, Technology Excellence (TE)

Rittigfeld 1, 91301 Forchheim, GERMANY

The Provision of Assembly, Packaging and Distribution Services for Components of Medical Imaging Devices (Computers)

Siemens Healthineers AG, Technology Excellence (TE)

Röntgenstr. 19-21, 95478 Kemnath, GERMANY

The Provision of Design and Development, Production, Assembly, Packaging and Distribution Services for Mechatronic Components for Medical Imaging Devices and In-Vitro Diagnostic Instruments

Siemens Healthineers AG, Technology Excellence (TE)

Röntgenstr. 2, 07407 Rudolstadt, GERMANY

The Provision of Design and Development, Production, Assembly, Packaging and Distribution Services of Components for Medical Imaging Devices (X-Ray Tubes, X-Ray Tube Cooling Units, X-Ray Tube Assemblies) and Linear Accelerators

Siemens X-Ray Vacuum Technology Ltd.

No.112, Meiyu Road, 214028 Wuxi, Jiangsu, PEOPLE'S
REPUBLIC OF CHINA

Design and Development, Production, Assembly, Packaging and Distribution for Components of Medical Imaging Devices (high voltage Generators and X-Ray Tube Assemblies)

Certificate

No. Q5 091596 0026 Rev. 09

Facility(ies):

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

The Provision of Design and Development, Production, Assembly, Packaging and Distribution Services for Mechatronic Components for Medical Imaging Devices and In-Vitro Diagnostic Instruments

Siemens Shenzhen Magnetic Resonance Ltd., Unit TC

Gaoxin C. Ave. 2nd, Hi-Tech Industrial Park, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

The Provision of Design and Development, Production, Assembly, Packaging and Distribution Services for Components of Medical Imaging Devices (PCB Assemblies, Assemblies and Computers)

Siemens Healthineers AG, X-Ray Products (XP)

Siemensstr. 1, 91301 Forchheim, GERMANY

Design and Development, Production, Distribution, Installation and Refurbishing of Imaging Systems utilizing Ionizing Radiation (X-Ray Systems) and related Medical Workplaces, Accessories and Software and Distribution of Accessories

Siemens Healthineers AG, Customer Services

Hartmannstr. 16, 91052 Erlangen, GERMANY

Customer Services and Customer Training for Medical Devices and related Hardware and Software



Product Service

Certificate

No. Q5 062575 0060 Rev. 03

Holder of Certificate: **Siemens Shanghai Medical Equipment Ltd.**
278 Zhou Zhu Road
201318 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development,
Production of X-ray Computed Tomography,
X-ray Diagnostic Equipment, Fluoroscopic and
Radiographic Equipment, Related Electric,
Electronic and Mechanical Components
for Medical Devices
(for detailed information see following pages)**

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Report No.: SH2107203

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Date, 2022-03-01

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 062575 0060 Rev. 03

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 Shanghai Medical Equipment Ltd. XP Facility
278 Zhou Zhu Road, 201318 Shanghai, PEOPLE'S REPUBLIC OF
CHINA

Design and Development, Production of X-ray Diagnostic
Equipment, Related Electric, Electronic and Mechanical
Components for Medical Devices

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

Design and Development, Production of X-ray Computed
Tomography, Related Electric, Electronic and Mechanical
Components for Medical Devices

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

Design and Development, Production of Fluoroscopic and
Radiographic Equipment, Related Electric, Electronic and
Mechanical Components for Medical Devices