

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Management Service

CERTIFICATE

Certificate Registration No.: 12 100 25280 TMS / Order No.: 70089898

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that the organization

Siemens Healthcare GmbH

Henkestr. 127
91052 Erlangen
Germany

for the scope

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; In-Vitro-Diagnostic Instruments

including the sites see enclosure

has established and applies a Quality Management System.

An audit was performed and has furnished proof that the requirements according to

DIN EN ISO 9001:2015

are fulfilled.

The certificate is valid from **2024-05-17** until **2027-05-15**.

Previous certificate valid until 2024-05-15.

Fred Wenke
Head of Certification Body
Munich, 2024-05-21

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Management Service

ENCLOSURE OF CERTIFICATE

Certificate Registration No.: 12 100 25280 TMS / Order No.: 70089898

certificate holder:

Siemens Healthcare GmbH
Henkestr. 127, 91052 Erlangen, Germany

at the sites	scope
Siemens Healthcare GmbH Henkestr. 127, 91052 Erlangen Germany	Global Head Quarter, Corporate Government Funktion.
Siemens Healthineers AG Siemensstr. 3, 91301 Forchheim Germany	Global Head Quarter, Corporate Government Funktion, Legal Manufacturer.
Siemens Healthineers AG Technology Excellence (TE) Henkestr. 127, 91052 Erlangen Germany	Design and Development, Production and Distribution of In-Vitro Diagnostics Instruments, X-ray Tube Housing Assemblies, Image Intensifiers, mechanical, electrical and electronical Assemblies (including non-medical applications), as well as Components, Sub-Systems, Systems for Diagnostic and Therapeutic Medical Devices including the applicable software Providing of Service –Activities in manufacturing-Environment.
Siemens Healthineers AG Technology Excellence (TE) Günther-Scharowsky-Str. 21, 91058 Erlangen Germany	
Siemens Healthineers AG Technology Excellence (TE) Röntgenstr. 19-21, 95478 Kernath Germany	
Siemens Healthineers AG Technology Excellence (TE) Röntgenstr. 2, 07407 Rudolstadt Germany	
Siemens Healthineers AG Magnetic Resonance (MR) Henkestr. 127, 91052 Erlangen Germany	Design and Development, Production and Distribution and Refurbishing of Systems and Components for Magnetic Resonance Devices and hybrid Magnetic Resonance and Molecular Imaging Devices including the Applicable Software.
Siemens Healthineers AG Computed Tomography (CT) Siemenstr. 1, 91301 Forchheim Germany	Design and Development, Production and Distribution and Refurbishing of Computed Tomography, Medical Components and Systems, Medical Workplaces and Software.

Fred Wenke
Head of Certification Body
Munich, 2024-05-21

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CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

ENCLOSURE OF CERTIFICATE

Certificate Registration No.: 12 100 25280 TMS / Order No.: 70089898

certificate holder:

Siemens Healthcare GmbH
Henkestr. 127, 91052 Erlangen, Germany

at the sites	scope
Siemens Healthineers AG Advanced Therapies (AT) 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 Healthineers AG Advanced Therapies (AT) Röntgenstr. 19-21, 95478 Kernath Germany	
Siemens Healthineers AG 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 Healthineers AG 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 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 Clinical Software Products, Picture Archiving and Communication Systems (PACS) - Software Components and Systems, Workplaces and Medical Workstations.
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 Clinical Software Products and Software Components.
Siemens Healthineers AG Technology Excellence (TE) Rittigfeld 1, 91031 Forchheim Germany	Production of mechanical, electrical and electronical Assemblies.

Fred Wenke
Head of Certification Body
Munich, 2024-05-21

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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)



Product Service

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



Product Service

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)



Product Service

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)



Product Service

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)



Product Service

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