

# EU DECLARATION OF CONFORMITY

of Regulation (EU) 2017/745

## Manufacturer

Name: Siemens Healthcare GmbH  
Address: Henkestr. 127  
91052 Erlangen  
Germany

Single Registration  
Number (SRN): DE-MF-000006122

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## Facility

Name: Siemens Healthineers AG  
Computed Tomography (CT)

Address 1: Siemensstr. 1  
91301 Forchheim  
Germany

Address 2: Rittigfeld 1  
91301 Forchheim  
Germany

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## Product Identification

Product/Trade Name: **SOMATOM go.Top**  
Model: 11061640  
Software Version: VB20  
Basic UDI-DI: 0405686900117UR  
UDI-DI: 04056869151571

## Nomenclature Code

GMDN Code: 37618  
GMDN Term: Full-body CT system

## Classification

Risk Class: Class IIb (according to rule 10 Annex VIII Medical Device Regulation (EU) 2017/745)

## Intended Purpose Statement under Regulation (EU) 2017/745:

Computed tomography system intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.

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We declare that the above medical device is in conformity with the following legislation(s):  
**Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices**

The conformity of the quality management system according to Article 52 and Annex IX chapter I and chapter III is certified by the following notified body:

TÜV SÜD Product Service GmbH  
Ridlerstrasse 65  
80339 Muenchen  
Germany

The identification number of the notified body for implementation of the procedure set out in Annex IX and Article 52 to the above regulation is: 0123

Identification of EU Quality Management Certificate: G10 091596 0052

Reference to Common Specifications: /

**Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment**

Relevant Harmonized Standard: EN IEC 63000:2018, IEC 63000:2016/AMD1:2022

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare GmbH.

Place and date Forchheim, 26. März 2025

Siemens Healthcare GmbH

Signature

Name

Dr. Philipp Fischer  
(Head of Unit CT)

Dr. Markus Nagel  
(Head of Unit CT Quality Management)

For conditions of warranty and liability please refer to the General Conditions of Sale.

# EU DECLARATION OF CONFORMITY

## Manufacturer

Name: Siemens Healthcare GmbH  
Address: Henkestr. 127  
91052 Erlangen  
Germany

Single Registration  
Number (SRN): DE-MF-000006122

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## Facility

Name: Siemens Healthcare GmbH  
Computed Tomography (CT)

Address: Siemensstr. 1  
91301 Forchheim  
Germany

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## Product Identification

Product/Trade Name: **syngo.via RT Image Suite**  
Model: 11664618  
Software Version: VB80  
Basic UDI-DI: 0405686901998X2  
UDI-DI: 04056869959009

## Nomenclature Code

GMDN Code: 40867  
GMDN Term: CT system application software

## Classification

Risk Class: Class IIb (according to rule 11 Annex VIII Medical Device Regulation (EU) 2017/745)

## Intended Purpose Statement under Regulation (EU) 2017/745:

Image analysis software for evaluating image data sets and preparing them for further use in therapy.

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We declare that the above medical device is in conformity with the following legislation(s):

**Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices**

The conformity of the quality management system according to Annex IX and Article 52 is certified by the following notified body:

TÜV SÜD Product Service GmbH  
Ridlerstrasse 65  
80339 Muenchen  
Germany

The identification number of the notified body for implementation of the procedure set out in Annex IX and Article 52 to the above regulation is: 0123

Identification of EC Certificate: G10 091596 0052

Reference to Common Specifications: /

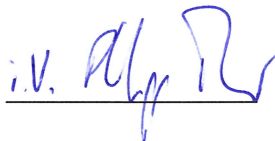
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This declaration of conformity is issued under the sole responsibility of Siemens Healthcare GmbH.

Place and date Forchheim, 10. Okt. 2023

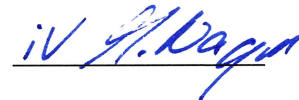
Siemens Healthcare GmbH

Signature



Name

Dr. Philipp Fischer  
(Head of Unit CT)



Dr. Markus Nagel  
(Head of Unit CT Quality Management)

For conditions of warranty and liability please refer to the General Conditions of Sale.



Product Service

# Certificate

**No. Q5 062575 0060 Rev. 04**

**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 and Production of X-ray Computed Tomography, X-ray Diagnostic Equipment, Fluoroscopic and Radiographic Equipment, Molecular Imaging Systems, Related Electric, Electronic and Mechanical Components, Medical Device Software Products and Software Components for Medical Devices**

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 062575 0060 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_062575_0060_Rev_04)

**Report No.:** SH25007201

**Valid from:** 2025-04-01

**Valid until:** 2028-03-31

**Date,** 2025-03-19

Christoph Dicks  
Head of Certification/Notified Body



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 062575 0060 Rev. 04

**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 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

**Siemens Shanghai Medical Equipment Ltd. MI facility**  
278 Zhou Zhu Road, 201318 Shanghai, PEOPLE'S REPUBLIC OF  
CHINA

Design and Development and Production of Molecular Imaging  
Systems, Related Electric, Electronic and Mechanical Components  
for Medical Devices



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 062575 0060 Rev. 04

## Facility(ies):

**Siemens Shanghai Medical Equipment Ltd. D&A facility**  
278 Zhou Zhu Road, 201318 Shanghai, PEOPLE'S REPUBLIC OF  
CHINA

Design and Development and Production of Medical Device  
Software Products and Software Components for Medical Devices



# 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



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 123518 0022 Rev. 00

**Holder of Certificate:** **Siemens Healthineers AG**

Siemensstr. 3  
91301 Forchheim  
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 Design and Development, Production, Assembly, Packaging and Distribution Services of Components for Medical Imaging Devices and 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 123518 0022 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_123518_0022_Rev.00)

**Report No.:** 713330787  
**Valid from:** 2025-03-28  
**Valid until:** 2028-03-27

**Date,** 2025-03-28

Christoph Dicks  
Head of Certification/Notified Body





Product Service

# Certificate

No. Q5 123518 0022 Rev. 00

**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 Healthineers AG**  
Siemensstr. 3, 91301 Forchheim, GERMANY  
  
Management, Regulatory Affairs, Regulatory Compliance, Audits

**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 and Hardware and Software for Computer Assisted Surgery and Radiology

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

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

**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





Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 123518 0022 Rev. 00

## Facility(ies):

### **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

### **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

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

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

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

### **Siemens Healthineers AG, Particle Therapy**

Simon-Hegele-Str. 5, 91301 Forchheim, GERMANY

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



Product Service

# Certificate

No. Q5 123518 0022 Rev. 00

## Facility(ies):

### **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)

### **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

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



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 123518 0022 Rev. 00

## Facility(ies):

### **Siemens Healthineers AG, Technology Excellence (TE)**

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

The Provision of 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

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

### **Siemens Healthineers AG, Technology Excellence (TE)**

An den Sandgruben 1, 91301 Forchheim, GERMANY

The Provision of Reuse, Packaging and Distribution Services for Components 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)



Product Service

# Certificate

No. Q5 123518 0022 Rev. 00

## 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

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

## 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



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 123518 0022 Rev. 00

## 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. 04**

**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 and Production of X-ray Computed Tomography, X-ray Diagnostic Equipment, Fluoroscopic and Radiographic Equipment, Molecular Imaging Systems, Related Electric, Electronic and Mechanical Components, Medical Device Software Products and Software Components for Medical Devices**

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 062575 0060 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_062575_0060_Rev_04)

**Report No.:** SH25007201

**Valid from:** 2025-04-01

**Valid until:** 2028-03-31

**Date,** 2025-03-19

Christoph Dicks  
Head of Certification/Notified Body



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 062575 0060 Rev. 04

**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 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

**Siemens Shanghai Medical Equipment Ltd. MI facility**  
278 Zhou Zhu Road, 201318 Shanghai, PEOPLE'S REPUBLIC OF  
CHINA

Design and Development and Production of Molecular Imaging  
Systems, Related Electric, Electronic and Mechanical Components  
for Medical Devices



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 062575 0060 Rev. 04

## Facility(ies):

**Siemens Shanghai Medical Equipment Ltd. D&A facility**  
278 Zhou Zhu Road, 201318 Shanghai, PEOPLE'S REPUBLIC OF  
CHINA

Design and Development and Production of Medical Device  
Software Products and Software Components for Medical Devices





## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 091596 0052 Rev. 01**

**Manufacturer:****Siemens Healthcare GmbH**

Henkestr. 127  
91052 Erlangen  
GERMANY

**SRN Manufacturer:**

DE-MF-000006122

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 091596 0052 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G10 091596 0052 Rev. 01)

**Report No.:**

713238995

**Preceding Certificate No.:**

G10 091596 0052 Rev. 00

**Valid from:**

2022-02-11

**Valid until:**

2025-09-29

**Date of Initial Issuance:**

2020-09-30

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2022-02-11



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 091596 0052 Rev. 01**

<b>Classification:</b>	IIb
<b>Device Group:</b>	Z110301 - DIGITAL ANGIOGRAPHY SYSTEMS
<b>Intended Purpose:</b>	Angiography system intended for angiography- and fluoroscopic-based procedures
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z11039017 - MOBILE RADIOSCOPIC UNITS
<b>Intended Purpose:</b>	Mobile X-ray system intended for angiography- and fluoroscopic-based procedures
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z120507 - CARDIOGRAPHY INSTRUMENTS
<b>Intended Purpose:</b>	Recording system intended for physiological, hemodynamic, and electrophysiological monitoring
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z110306 - COMPUTED TOMOGRAPHS (CT)
<b>Intended Purpose:</b>	Computed tomography system intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z110302 - MAMMOGRAPHY SYSTEMS
<b>Intended Purpose:</b>	X-Ray system that generates full-field digital mammography images as well as tomosynthesis images for various procedures
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z110311 - DIRECT DIGITAL RADIOLOGY (DR) SYSTEMS
<b>Intended Purpose:</b>	Stationary X-ray system intended for various procedures that visualizes a variety of anatomical structures
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z11069092 - VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS - MEDICAL DEVICE SOFTWARE
<b>Intended Purpose:</b>	Software solutions intended to process, communicate, display, read, and archive medical data for informing and driving clinical management
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z11030192 - DIGITAL ANGIOGRAPHY SYSTEMS - MEDICAL DEVICE SOFTWARE
<b>Intended Purpose:</b>	Medical software intended for angiography- and fluoroscopic-



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 091596 0052 Rev. 01**

based procedures.

**Classification:** IIb  
**Device Group:** Z11039012 - X-RAY TUBE ASSEMBLY  
**Intended Purpose:** X-ray tube assembly intended to be integrated into X-ray imaging systems for medical purposes

**Classification:** IIb  
**Device Group:** Z11030292 - MAMMOGRAPHY SYSTEMS - MEDICAL DEVICE SOFTWARE  
**Intended Purpose:** Medical software that provides workflow, reading and reporting support on clinical images

**Classification:** IIb  
**Device Group:** Z11030692 - COMPUTED TOMOGRAPHS (CT) - MEDICAL DEVICE SOFTWARE  
**Intended Purpose:** Image analysis software for evaluating image data sets and preparing them for further use in therapy

**Classification:** IIb  
**Device Group:** Z11039009 - FLUOROSCOPY DEVICES  
**Intended Purpose:** Radiographic and fluoroscopic X-ray system intended for various procedures that visualizes a variety of anatomical structures

**Classification:** IIb  
**Device Group:** Z11039016 - MOBILE RADIOGRAPHIC UNITS  
**Intended Purpose:** Mobile X-ray system intended for various procedures that visualizes a variety of anatomical structures

**Classification:** IIa  
**Device Group:** Z11030682 - COMPUTED TOMOGRAPHS (CT) - SOFTWARE ACCESSORIES  
**Intended Purpose:** -

**Classification:** IIa  
**Device Group:** Z110501 - MAGNETIC RESONANCE (MR) SYSTEMS  
**Intended Purpose:** -

**Classification:** IIa  
**Device Group:** Z12040192 - GENERAL MEDICINE DIAGNOSIS AND MONITORING INSTRUMENTS - MEDICAL DEVICE SOFTWARE



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 091596 0052 Rev. 01**

**Intended Purpose:** -

**The validity of this certificate  
depends on conditions and/or  
is limited to the following:** - none -

Revision History:	Rev.	Dated	Report
	00	2020-09-30	713172833



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 062575 0074 Rev. 01**

**Manufacturer:**

**Siemens Shanghai Medical  
Equipment Ltd.**

278 Zhou Zhu Road  
201318 Shanghai  
PEOPLE'S REPUBLIC OF CHINA

**SRN Manufacturer:**

Not available at issuance date of this certificate.

**Authorized  
Representative:**

Siemens Healthcare GmbH  
Henkestr. 127, 91052 Erlangen, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 062575 0074 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G10 062575 0074 Rev. 01)

**Report No.:**

SH2107201

**Preceding Certificate No.:**

G10 062575 0074 Rev. 00

**Valid from:**

2021-09-03

**Valid until:**

2025-11-05

**Date of Initial Issuance:**

2020-11-06

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2021-09-03



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 062575 0074 Rev. 01**

<b>Classification:</b>	IIb		
<b>Device Group:</b>	Z110306 - COMPUTED TOMOGRAPHY SCANNING SYSTEMS (CT)		
<b>Intended Purpose:</b>	Computed tomography system intended to generate and process cross-sectional images of patients by computer reconstruction of x-ray transmission data.		
<b>Classification:</b>	IIb		
<b>Device Group:</b>	Z110311 - DIRECT DIGITAL X-RAY SYSTEMS		
<b>Intended Purpose:</b>	Stationary X-ray system intended for various procedures that visualizes a variety of anatomical structures.		
<b>Classification:</b>	IIb		
<b>Device Group:</b>	Z110390 - VARIOUS DIAGNOSTIC AND INTEROPERATIVE BIOIMAGING INSTRUMENTS		
<b>Intended Purpose:</b>	Mobile X-ray system intended for angiography-and fluoroscopic-based procedures.		
<b>Classification:</b>	IIb		
<b>Device Group:</b>	Z110307 - RADIOGRAPHIC/FLUOROSCOPIC TABLE SYSTEMS		
<b>Intended Purpose:</b>	Radiographic and fluoroscopic X-ray system intended for various procedures that visualizes a variety of anatomical structures.		
<b>The validity of this certificate depends on conditions and/or is limited to the following:</b>	-none-		
<b>Revision History:</b>	Rev. 00	Dated 2020-11-06	Report SH1907202