

CERTIFICATE

The Certification Body of TÜV SÜD Management Service GmbH

certifies that

Siemens Healthcare GmbH

Henkestr. 127 91052 Erlangen, Germany

has established and applies a Quality Management System for

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 facilities see enclosure (for detailed information see following pages).

An audit was performed, Order No. 70089898.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2021-11-15** until **2024-05-15**. Certificate Registration No.: **12 100 25280 TMS**.

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Head of Certification Body Munich, 2021-11-17



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CERTIFICATE



Enclosure of Certificate Registration No.: 12 100 25280 TMS

Facilities and their scope of application

Siemens Healthcare GmbH, Advanced Therapies

Siemensstr. 1, 91301 Forchheim, Germany Roentgenstr. 19-21, 95478 Kemnath, Germany

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

Siemens Healthcare GmbH, Particle Therapy

Hofmannstr. 26, 91052 Erlangen, Germany

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

Siemens Healthcare GmbH, Radiation Oncology

Doris-Ruppenstein-Str. 4, 91052 Erlangen, Germany Roentgenstr. 19-21, 95478 Kemnath, Germany

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

Siemens Healthcare GmbH, Technology Centers (TC)

Henkestr. 127, 91052 Erlangen, Germany Guenther-Scharowsky-Str. 21, 91058 Erlangen, Germany Siemensstr. 1, 91301 Forchheim, Germany Roentgenstr. 19-21, 95478 Kemnath, Germany Roentgenstr. 2, 07407 Rudolstadt, 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 Healthcare GmbH, Technology Centers (TC) Rittigfeld 1, 91301 Forchheim, Germany

Production of mechanical, electrical and electronical Assemblies

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Facilities and their scope of application

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

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, 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 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 GmbH, X-Ray Products (XP)

Siemensstr. 1, 91301 Forchheim, Germany

Design and Development, Production and 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

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Head of Certification Body Munich, 2021-11-17



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