

# 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 **2021-05-16** until **2024-05-15**. Certificate Registration No.: **12 100 25280 TMS**.

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Head of Certification Body Munich, 2021-05-25



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#### **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 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

#### Siemens Healthcare, S.L.

Avenida Leonardo da Vinci, 15, 28906 Getafe, Spain

Design and Development 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

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# Enclosure of Certificate Registration No.: 12 100 25280 TMS

Facilities and their scope of application

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 Siemens Shanghai Medical Equipment Ltd., Unit TC 278 Zhouzhu Road, 201318 Shanghai, P.R. China Siemens X-Ray Vacuum Technology Ltd. No. 112, Meiyu Road, 214028 Wuxi, Jiangsu, P.R. China Siemens Shenzhen Magnetic Resonance Ltd. (TC) Gaoxin C. Ave 2<sup>nd</sup>, Hi-Tech Industrial Park, 518057 Shenzhen, P.R. China

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

Siemens Shenzen Magnetic Resonance Ltd. Hong Fa Yuan Tang Tou Logistics Park 1st Building, 518108 Shenzen, P.R. China

Logistic, Warehouse

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

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## Enclosure of Certificate Registration No.: 12 100 25280 TMS

Facilities and their scope of application

Siemens Healthcare GmbH, SYNGO (SY) Siemensstr. 1, 91301 Forchheim, Germany Siemens Medical Solutions USA, Inc. 65 Valley Stream Parkway, Malvern, PA 19355, USA 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 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 N2K 3S2, Canada

Design and Development 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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