ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

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

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

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

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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

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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

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