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ZERTIFIKAT ◆ СЕРТИФИКАТ ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICA

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

TÜV SÜD
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 105957 0004 Rev. 00

Manufacturer:

Siemens Healthcare Pvt. Ltd.
Unit No. 9A, 9th Floor, North Tower
Godrej One, Pirojshanagar, Vikhroli East
Mumbai 400 079
INDIA

SRN Manufacturer: IN-MF-000011828

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 105957 0004 Rev. 00

Report No.: 713188304

Valid from: 2022-08-05
Valid until: 2027-08-04

Issue date: 2022-08-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G10 105957 0004 Rev. 00

Classification:	IIb
Device Group:	Z11039017 - MOBILE RADIOSCOPIC UNITS
Intended Purpose:	Mobile X-ray system intended for angiography- and fluoroscopic-based procedures
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

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