EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.:	HZ 2365675-1
Manufacturer:	**Shimadzu Corporation, Medical Systems Division** 1 Nishinokyo-Kuwabaracho Nakagyo-ku, Kyoto 604-8511 Japan
EUDAMED Single Registration No.:	Not Registration number available yet.
Products:	Products of class IIb: Z110307 - DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY INSTRUMENTS REMOTE CONTROL TABLES Intended Purpose: multi-purpose X-ray R/F system suitable for radiographic and fluoroscopic examinations, including general radiography and pediatric examinations, excluding mammography.yw Z110305 - DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY INSTRUMENTS RADIOLOGY INSTRUMENTS Intended Purpose: Applied to X-ray radiography for each region of patients usually in the laying down on the table top when combined with an X-ray high voltage generator, an X-ray tube unit, an X-ray collimator, and if necessary, an X-ray tube support, and digital radiography system.
Authorised representative(s):	Shimadzu Europa GmbH Albert-Hahn-Strasse 6-10, 47269 Duisburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial	2022-08-30

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	150128609-360
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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Digitally signed by Botnaru Andrei
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