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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 2251444-1
Manufacturer:	**FUJIFILM Healthcare Corporation** 2-1, Shintoyofuta, Kashiwa-shi, Chiba 277-0804 Japan
EUDAMED Single Registration No.:	JP-MF-000018708
Products:	Products of class IIb: Z110306 - DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY INSTRUMENTS COMPUTED TOMOGRAPHS (CT) Intended Purpose: This system is intended to use at any part of the whole body to get computed tomography images and those images are used for diagnostic purposes.
Authorised representative(s):	**FUJIFILM Healthcare Deutschland GmbH** Otto - von - Guericke - Ring 3, 65205 Wiesbaden, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-09-28

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.:	150246261-307
Effective date:	2023-09-28
Expiry date:	2028-09-27
Issue date:	2023-09-28

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG
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.