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 1194536-1

Manufacturer: **FUJIFILM Corporation**
26-30, Nishiazabu 2-chome,
Minato-ku, Tokyo
106-8620 Japan

EUDAMED Single Registration No.: JP-MF-000010401

Products: Products of class IIa:

Z120206 - LOWER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Z120204 - ACQUISITION AND MANAGEMENT INSTRUMENTS FOR ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Z120782 - GASTROENTEROLOGY INSTRUMENTS - SOFTWARE
Z110311 - DIRECT DIGITAL RADIOLOGY (DR) SYSTEMS
Z110690 - VARIOUS DIGITAL BIOIMAGING MANAGEMENT INSTRUMENTS
Z120205 - UPPER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS
Z120208 - PULMONARY ENDOSCOPIC INSTRUMENTS
Z110402 - ULTRASOUND PROBES
Z110401 - ULTRASOUND SCANNERS
Z120290 - VARIOUS ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY INSTRUMENTS
Z120210 - ENT ENDOSCOPY INSTRUMENTS
Z110602 - DIGITAL COMPUTED RADIOGRAPHY (CR) SYSTEMS

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.: 150263416-307

Effective date: 2022-12-18

Expiry date: 2025-10-27

Issue date: 2022-12-18

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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

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 1194536-1

Manufacturer: **FUJIFILM Corporation**
26-30, Nishiazabu 2-chome,
Minato-ku, Tokyo
106-8620 Japan

Products of class IIb:

Z110390 - DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY INSTRUMENTS
VARIOUS INSTRUMENTS FOR RADIODIAGNOSTICS AND INTERVENTIONAL PROCEDURES
Intended purpose: The DR-XD 3000 is a fluoroscopic and radiographic system intended to visualize human anatomical structures.

Authorised representative(s): FUJIFILM Europe GmbH
Balcke-Duerr-Allee 6, 40882 Ratingen, Germany

Certificate history		
Revision:	Description:	Issue date:
1	Initial issue	2021-09-29
2	Added product Z120782	2021-11-02
3	Added product Z110311, Z110690	2021-11-18
4	Added product Z120205, Z120208, Z110402, Z110401	2021-12-28
5	Added product Z120290	2022-02-25
6	Change of authorised representative address	2022-03-29
7	Added product Z120210, Z110602	2022-05-25
8	Added product Z110390	2022-12-18

Report No.: 150263416-307

Effective date: 2022-12-18

Expiry date: 2025-10-27

Issue date: 2022-12-18

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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