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 2003379-1

Manufacturer: **KONICA MINOLTA, INC.**
1 Sakura-machi, Hino-shi, Tokyo,
191-8511 Japan

Digitally signed by Chicu Natalia
Date: 2026.03.06 12:32:18 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EUDAMED Single Registration No.: JP-MF-000008214

Products: Products of class IIa:

Z110603 - PICTURE ARCHIVING AND COMMUNICATION SYSTEMS
Z110401 - ULTRASOUND SCANNERS
Z110311 - DIRECT DIGITAL X-RAY SYSTEMS
Z11031182 - DIRECT DIGITAL X-RAY SYSTEMS – SOFTWARE
Z110402 - ULTRASOUND PROBES

Authorised representative(s): Konica Minolta Business Solutions Europe GmbH
Capellalaan 65, 2132 JL, Hoofddorp, The Netherlands

Certificate history		
Revision:	Description:	Issue date:
1	Initial issue	2021-07-21
2	Added code Z110311 and Z11031182	2021-09-01
3	Added code Z110402	2023-08-01

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.: 150278697-307

Effective date: 2023-08-01

Expiry date: 2026-07-20

Issue date: 2023-08-01

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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

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