SHIMADZU

CE 0197

This medical device also complies with RoHS directive.

ZCCM-0127

EU Declaration of Conformity

This Declaration of Conformity is related to each product release.

Manufacturer	:	**Shimadzu Corporation**
Address	:	**1, Nishinokyo Kuwabara-cho, Nakagyo-ku, Kyoto, 604-8511, Japan**
SRN	:	**JP-MF-000025145**

declares, in sole responsibility, that the following product

Product Name	:	**X-ray tube assembly [J-series, see Annex A]**
Parts Number	:	**See Annex A**
MDR Classification:		**IIb (Rule10)**
Basic UDI-DI	:	**454021702000000000000002U5**
Intended purpose	:	**See Annex B**
EMDN code	:	**Z11039012**

are compliant with the following regulation, directive and standards.

Regulation and Directive

REGULATION (EU) 2017/745 on medical devices (abbreviated as MDR)

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (as amended by Directive (EU) 2015/863) (abbreviated as RoHS)

Standards:

MDR: EN 60601-1:2006+A1:2013+A12:2014
EN 60601-1-3:2008+A1:2013
EN ISO 14971:2019+A11:2021
EN ISO 15223-1:2021
EN 60601-1-2:2015
EN 60601-2-28:2019
EN 1041:2008+A1:2013

RoHS: EN IEC 63000:2018

The company's Quality System complies with the requirements of **Annex IX (MDR)**, which is certified by **TUV Rheinland LGA Products GmbH**;
Tillystrasse 2, 90431 Nuremberg, Germany **(Notified under No. 0197)** as **Registration No.: HZ 2365675-1**

The company named above will keep on file for review the following technical documentation:
*operating and maintenance instructions
*technical drawings
*description of measures designed to measure conformity
*other technical documentation, e.g. quality assurance measures for design and production

Importer and Authorized Representative in EU
Shimadzu Europa GmbH
Albert-Hahn-Strasse 6-10, 47269 Duisburg, Germany

Note: This declaration becomes invalid if technical or operational modifications are introduced without the manufacturer's consent.

Refer to Technical file for **MDR: ZCCE-0127A / RoHS: ZCCR-0002G**

The objects which become valid for this declaration, refer to manufacturer's record of this product.

26, Mar. 2025 (issued date)
Kyoto, Japan (Place)

K Kataoka (signature)
Koichi Kataoka (full name)
General Manager, Quality Assurance Department,
Medical Systems Division,
Shimadzu Corporation

Digitally signed by Botnaru Andrei
Date: 2026.01.29 13:17:27 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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Annex A

Product Name	Parts Number	Note
X-ray tube assembly 0.4/0.7JG326D-265	582-24838-02	
X-ray tube assembly 0.7/1.2JG326D-265	582-24825-02	
X-ray tube assembly 0.7/1.2JG326D-265	582-24825-04	
X-ray tube assembly 0.6/1J327C-280	582-24496-22	
X-ray tube assembly 0.6/1J317C-282	582-24499-01	
X-ray tube assembly 0.6/1J317C-282	582-24499-02	

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Annex B

Intended purpose of X-ray tube assembly J-series is as follows.

This equipment is intended to be used as an X-ray tube assembly for medical diagnosis for radiographic and fluoroscopic examinations.