

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 : **4540217020000000000002U5**
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 60601-1-2:2015
EN 60601-1-3:2008+A1:2013 EN 60601-2-28:2019
EN ISO 14971:2019+A11:2021 EN 1041:2008+A1:2013
EN ISO 15223-1:2021

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

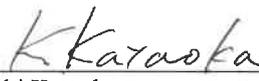
Albert-Hahn-Strasse 6-10, 47269 Duisburg, Germany

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)



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



This medical device also complies with RoHS directive.

ZCCM-0127

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	



This medical device also complies with RoHS directive.

ZCCM-0127

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.