

EC Declaration of conformity

This Declaration of Conformity is related to each product release.

According to **Medical Device Directive 93/42/EEC as amended by 2007/47/EC**

Manufacturer : **SHIMADZU CORPORATION**
Medical Systems Division
Address : **1,NISHINOKYO-KUWABARACHO,**
NAKAGYO-KU, KYOTO, 604-8511, JAPAN

declares, in sole responsibility, that the following product

Product Name : **X-ray tube assembly**
Model Name : **X-ray tube assembly [J-series and JG-series, see below]**
Parts Number : **0.4/0.7JG326D-265 582-24838-02, 582-24838-11, 582-24838-51**
0.7/1.2JG326D-265 582-24825-02, 582-24825-04, 582-24825-42, 582-24825-51
0.6/1J327C-280 582-24496-22
0.6/1J317C-282 582-24499-02
MDD Classification: **IIb (Rule10)**
GMDN Code : **35618**
UMDNS Code : **15975**

are compliant with **Annex I for 93/42/EEC as amended by 2007/47/EC**

and compliant with the following harmonized standards.

EN 60601-1:2006+A11+A12
EN 60601-1-2:2007
EN 60601-1-3:2008
EN 60601-2-28:2010
EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2008

The company's Quality System complies with the requirements of **Annex II, excluding Section 4 for 93/42/EEC as amended by 2007/47/EC**, which is certified by **TUV Rheinland LGA Products GmbH;**

Tillystrasse 2, 90431 Nuremberg, Germany (**Notified under No. 0197**) as **Registration No.: HD 60147504 0001**

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/Distributor 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 J series ZCCE-0012Y

16. July 2021 (issued date)

Kyoto, Japan (place)



(signature)

Koichi Kataoka (full name)
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Medical Systems Division,
Shimadzu Corporation