

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 [P-series, see below]**
 Parts Number :

0.6/1.2P33DK-85	582-24477-50, 582-24477-57	0.6/1.2P13DK-85	582-24476-50
0.6/1.2P324DK-85	582-24486-50, 582-24486-57	0.6/1.2P164DK-85	582-24487-50
0.6/1.2P364DK-85	582-24488-50, 582-24488-57	0.6/1.2P18DE-85	582-24556-50
0.6/1.2P324DK-125	582-24490-50, 582-24490-57	0.6/1.2P323DK-85	582-24566-50
0.6/1.2P364DK-125	582-24491-50, 582-24491-57	0.3/0.8P323DK-85	582-24564-50
0.6/1.2P38DE-85	582-24558-50, 582-24558-57	0.6/1.2P123DK-85	582-24492-50
1/2P18DK-85	582-24480-50	1/2P13DK-85	582-24560-50
1/2P33D-85	582-24562-50	0.2/0.8P39CK-85	582-24489-50
0.3/0.8P18DK-85	582-24483-50	0.3/0.8P324DK-85	582-24484-50
1/2P38D-85	582-24481-50	0.2/0.8P38C-85	582-24482-50
0.8P323DK-85	582-24565-50	0.8P324DK-85	582-24485-50
0.6/1.2P326D-150	582-50300-50, 582-50300-57	0.6/1.2P366D-150	582-50301-50, 582-50301-57

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+A1+A12	EN 60601-1-3:2008+A1	EN 60601-2-28:2019
EN ISO 14971:2012	EN 1041:2008	EN ISO 15223-1:2016

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 X-ray tube assembly P-series ZCCE-0058R

16. July 2021 (issued date) K Kataoka (signature)

Kyoto, Japan (place) Koichi Kataoka (full name)

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 Medical Systems Division,
 Shimadzu Corporation