SHIMADZU

CE 0197

ZCCM-0058J

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)
General Manager, Quality Assurance Department,
Medical Systems Division,
Shimadzu Corporation

Digitally signed by Botnaru Andrei
Date: 2026.01.26 12:04:29 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ