

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 :	P-series	
Parts Number :		
0.6/1.2P33DK-85	(532-24477, 582-24477, 582-24477-07)	0.6/1.2P13DK-85 (532-24476, 582-24476)
0.6/1.2P324DK-85	(532-24486, 582-24486, 582-24486-07)	0.6/1.2P164DK-85 (532-24487, 582-24487)
0.6/1.2P364DK-85	(532-24488, 582-24488, 582-24488-07)	0.6/1.2P18DE-85 (532-24556, 582-24556)
0.6/1.2P324DK-125	(532-24490, 582-24490, 582-24490-07)	0.6/1.2P323DK-85 (532-24566, 582-24566)
0.6/1.2P364DK-125	(532-24491, 582-24491, 582-24491-07)	0.3/0.8P323DK-85 (532-24564, 582-24564)
0.6/1.2P38DE-85	(532-24558, 582-24558, 582-24558-07)	0.5/1P13C-85 (532-24478, 582-24478)
0.6/1.2P123DK-85	(532-24492-02, 582-24492-02)	1/2P18DK-85 (532-24480, 582-24480)
1/2P13DK-85	(532-24560, 582-24560)	1/2P33D-85 (532-24562, 582-24562)
0.5/1P33C-85	(532-24479, 582-24479)	0.2/0.8P39CK-85 (532-24484, 582-24484)
0.3/0.8P18DK-85	(532-24483, 582-24483)	0.3/0.8P324DK-85 (532-24484, 582-24484)
1/2P38D-85	(532-24481, 582-24481)	0.2/0.8P38C-85 (532-24482, 582-24482)
0.8P323DK-85	(532-24565, 582-24565)	0.8P324DK-85 (532-24485, 582-24485)
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
EN 60601-1-2:2007
EN 60601-1-3:2008
EN 60601-2-28:2010
EN ISO 14971:2012
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 60130116 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

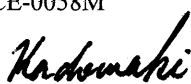
Importer/Distributor and Authorized Representative in EU

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 P series ZCCE-0058M

29. Oct. 2018 (issued date)

 (signature)
Toshio Kadowaki (full name)

General Manager, Quality Assurance Dept. Medical Systems Div. Shimadzu Corporation