⊕ SHIMADZU

CE 0197
ZCCM-0029N

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	:	**Mobile X-ray System**
Model Name	:	**Mobile X-ray System MUX-10 / MUX-10J**
Parts Number	:	**563-48510-64, 563-48510-74,**
		563-48510-75
MDD Classification :		**IIb (Rule10)**
GMDN Code	:	**37626**
UMDNS Code	:	**13272**

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 60601-1-6:2010
EN 60601-2-54:2009
EN 60627:2001
EN 62304:2006+AC2008
EN 62366:2008
EN ISO 10993-1:2009
EN ISO 14971:2012
EN ISO 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   MUX-10, MUX-10J   ZCCE-0029L

8. Aug. 2022 (issued date)	K. Kataoka (signature)
Kyoto, Japan (place)	Koichi Kataoka (full name)
	General Manager, Quality Assurance Department, Medical Systems Division, Shimadzu Corporation