SHIMADZU

CE 0197

ZCCM-0104Y

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	:	**SURGICAL MOBILE C-ARM IMAGING SYSTEM**
Model Name	:	**SURGICAL MOBILE C-ARM IMAGING SYSTEM OPESCOPE ACTENO**
Parts Number	:	**566-24400-07, 566-24400-11, 566-24400-14,**
		566-24400-51, 566-24400-53, 566-24400-55, 566-24400-59,
		566-24400-27, 566-24400-31, 566-24400-34,
		566-24400-71, 566-24400-73, 566-24400-75, 566-24400-79
		566-28800-61, 566-28800-62, 566-28800-82, 566-28800-83
MDD Classification	:	**IIb (Rule10)**
GMDN Code	:	**37646**
UMDNS Code	:	**16597**

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 60601-2-43:2010,	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 OPESCOPE ACTENO ZCCE-0104M

17. Oct. 2022 (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: 2023.08.16 12:34:06 EEST
Reason: MoldSign Signature
Location: Moldova