

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 : **Ib (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)  (signature)
Kyoto, Japan (place) **Koichi Kataoka** (full name)
General Manager, Quality Assurance Department,
Medical Systems Division,
Shimadzu Corporation