

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 MobileDaRt Evolution**
MOBILE X-RAY SYSTEM MobileArt Evolution
Parts Number : **MobileDaRt Evolution**

563-77777-21, 563-77777-22, 563-77777-23, 563-77777-27,
563-77777-28, 563-77777-29, 563-79000-21, 563-79000-22,
563-79000-23, 566-19200-01, 566-19200-03, 566-19200-21,
566-19200-31, 566-19888-01, 566-19888-03, 566-19888-21,
566-19888-31, 566-19888-41, 566-20000-05, 566-20000-06,
566-20000-07

MobileArt Evolution

563-77777-61, 563-77777-62, 563-77777-63, 563-77777-64,
563-77777-65, 563-77777-66, 566-19200-61, 566-19200-64,
566-19888-71, 566-19888-72, 566-19888-73, 566-19888-74,
566-19888-75, 566-19888-76

MDD Classification : **IIb (Rule10)**
GMDN Code : **37647**
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.

MDD : EN 60601-1:2006, EN 60601-1-2:2007, EN 60601-1-3:2008, EN 60601-1-6:2010,
EN 60601-2-54:2009, EN 60627:2001, EN 62366:2008, EN 62220-1:2004,
EN ISO 10993-1:2009, EN ISO 14971:2012, EN ISO 1041:2008,
EN ISO 15223-1:2016, EN 62304:2006+AC2008

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 MobileDaRt Evolution / MobileArt Evolution ZCCE-0077AN

9, Dec. 2019 (issued date)



(signature)

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General Manager, Quality Assurance Department
Shimadzu Corporation