SHIMADZU

Digitally signed by Botnaru Andrei
Date: 2024.02.09 10:54:36 EET
Reason: MoldSign Signature
Location: Moldova

CE 0197

ZCCM-0106AD

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	:	**Digital Angiography System**
Model Name	:	**Digital Angiography System Trinias**
Parts Number	:	**563-79820-24, 563-79820-25, 563-79820-26, 563-79821-24, 563-79821-25, 563-79821-26, 563-79822-24, 563-79823-24, 563-79830-24, 563-79830-25, 563-79830-26, 563-79831-24, 563-79831-25, 563-79831-26, 563-79832-24, 563-79832-25, 563-79832-27, 563-79832-28, 563-79840-24, 563-79840-27, 563-79861-07, 563-79861-08, 563-79861-27, 563-79861-28, 563-79861-47, 563-79861-48, 563-79863-07, 563-79863-08, 563-79863-27, 563-79863-28, 563-79863-47, 563-79863-48, 563-79863-77, 563-79863-78, 563-79863-87, 563-79863-88, 563-79863-97, 563-79863-98, 563-79864-07, 563-79864-27, 563-79864-47 563-79864-77, 563-79864-87, 563-79864-97**
MDD Classification:		**IIb (Rule10)**
GMDN Code	:	**37623**
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.

MDD :	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 60627:2001,
	EN 62366:2008,	EN 62220-1:2004,	EN 62220-1-3:2008,
	EN ISO 14971:2012,	EN ISO 15223-1:2016,	EN ISO 1041:2008,
	EN ISO 10993-1:2009,	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 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 Trinias ZCCE-0065AK

26. Dec. 2022 (issued date)

Kyoto, Japan (place)

K Kataoka (signature)

Koichi Kataoka (full name)
General Manager, Quality Assurance Department,
Medical Systems Division,
Shimadzu Corporation