SHIMADZU

Digitally signed by Botnaru Andrei
Date: 2023.08.16 12:32:48 EEST
Reason: MoldSign Signature
Location: Moldova

CE 0197

ZCCM-0060AD

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 : **REMOTE-CONTROLLED R/F SYSTEM**
Model Name : **REMOTE-CONTROLLED R/F SYSTEM FLEXAVISION**
Parts Number : **566-19600-01, -02, -03, -04, -05, -06, -07, -08, -09, -10, -11, -12**
566-19600-13, -14, -15, -16, -17, -18, -19, -20, -21, -22, -23, -24
566-28000-01, -02, -03, -04, -05, -06, -07, -08, -09, -10, -11, -12
566-28000-13, -14, -15, -16, -17, -18, -19, -20, -21, -22, -23, -24
566-19600-49, -50, -51, -52, -53, -54, -55, -56, -57, -58, -59, -60
566-19600-61, -62, -63, -64, -65, -66, -67, -68, -69, -70, -71, -72
566-28000-61, -62, -63, -64, -65, -66, -67, -68, -69, -70, -71, -72
566-19600-73, -74, -75, -76, -77, -78, -79, -80, -81, -82, -83, -84
566-28000-73, -74, -75, -76, -77, -78, -79, -80, -81, -82, -83, -84
566-28000-49, -50, -51, -52, -53, -54, -55, -56, -57, -58, -59, -60

MDD Classification : **IIb (Rule10)**
GMDN Code : **37679**
UMDNS Code : **16885**

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+A1+A12,	EN 60601-1-2:2015,	EN 60601-1-3:2008+A1+A11,
EN 60601-1-6:2010+A1,	EN 60601-2-54:2009+A1,	EN 60627:2001,
EN 62366:2008,	EN 62220-1:2004,	EN 62220-1-3:2008,
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 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 FLEXAVISION ZCCE-0060AH

21, Oct 2022 (issued date) K Kataoka (signature)

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