SHIMADZU

CE 0197

ZCCM-0107D

CE 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	:	**Radiography System**
Model Name	:	**Radiography System RADspeed fit**
Parts Number	:	**566-12700-01, 566-12700-11**
MDD Classification	:	**IIb (Rule10)**
GMDN Code	:	**37644**
UMDNS Code	:	**18430**

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
EN 60601-1-2:2007
EN 60601-1-3:2008
EN 60601-1-6:2010
EN 60601-2-54:2009
EN 60627:2001
EN 62304:2006+AC2008
EN 62366:2008
EN 62220-1:2004
EN ISO 10993-1:2009
EN ISO 14971:2012
EN 980:2008
EN ISO 1041:2008

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, D-90431 Nurnberg, Germany **(Notified under No. 0197)** as **Registration No.: HD 60104281 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, F.R. Germany
Note: This declaration becomes invalid if technical or operational modifications are introduced without the manufacturer's consent.

Refer to

Technical file for RADspeed fit ZCCE-0107D

4, Oct. 2016 (issued date) Kadowaki (signature)

Toshio Kadowaki (full name)
General Manager, Quality Assurance Dept.
Medical Systems Div.
Shimadzu Corporation

Digitally signed by Botnaru Andrei
Date: 2019.02.13 15:13:33 EET
Reason: MoldSign Signature
Location: Moldova