SHIMADZU

CE 0197
This medical device also complies with RoHS directive.

ZCCM-0125

EU Declaration of Conformity

This Declaration of Conformity is related to each product release.

Manufacturer	:	**SHIMADZU CORPORATION**
Address	:	**1,NISHINOKYO-KUWABARACHO, NAKAGYO-KU, KYOTO, 604-8511, JAPAN**
SRN	:	**JP-MF-000025145**

declares, in sole responsibility, that the following product

Product Name	:	**RADspeed Pro**
Parts Number	:	**See Annex A**
MDR Classification:		**IIb (Rule10)**
Basic UDI-DI	:	**4540217010000000000003SQ**
Intended purpose	:	**See Annex B**
EMDN code	:	**Z110305**

are compliant with the following regulation, directive and standards.

Regulation and Directive
REGULATION (EU) 2017/745 on medical devices (abbreviated as MDR)
DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (as amended by Directive (EU) 2015/863) (abbreviated as RoHS)
DIRECTIVE 2013/59/EURATOM

Standards:

MDR:
EN 60601-1:2006+A1:2013+A12:2014
EN 60601-1-3:2008+A1:2013+A11:2016
EN 60601-2-54:2009+A1:2015+A2:2019
EN 62366-1:2015+A1:2020
EN ISO 14971:2019+A11:2021
EN ISO 15223-1:2021
EN 62220-1-1:2015
EN 60601-1-2:2015+A1:2021
EN 60601-1-6:2010+A1:2015
EN 60627:2015
EN ISO 10993-1:2020
EN 1041:2008+A1:2013
EN 62304:2006+A1:2015

RoHS: EN IEC 63000:2018

The company's Quality System complies with the requirements of **Annex IX (MDR)**, which is certified by **TUV Rheinland LGA Products GmbH**;
Tillystrasse 2, 90431 Nuremberg, Germany **(Notified under No. 0197)** as **Registration No.: HZ 2365675-1**

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 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 **MDR: ZCCE-0125A / RoHS: ZCCR-0023AM**

The objects which become valid for this declaration, refer to manufacturer's record of this product.

20. May 2024 (issued date)
Kyoto, Japan (Place)

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

Digitally signed by Botnaru Andrei
Date: 2024.12.05 10:03:31 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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Annex A

Product Name	Parts Number	Note
RADspeed Pro	566-26000-50	
	566-26000-53	
	566-26000-54	
	566-26000-61	
	566-26000-62	
	566-26000-63	
	566-26000-64	
	566-26000-65	

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Annex B

Intended purpose of RADspeed Pro is as follows.

The RADspeed Pro is an X-ray radiography system used for the radiography of patients while they are standing or laying down.
A wide range of applications are offered including digital radiography with portable FPDs, as well as general radiography with a CR cassette or X-ray film cassette.