



ZCCM-0070AP

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 Radiography System, General Radiography System**
Model Name : **RADspeed Pro**
Parts Number : **566-18100-01, -02, -03, -06, -21, -22, -23,**
566-26000-01, -02, -03, -04, -20, -21, -30, -31, -32, -33, -40, -41, -42, -43
MDD Classification : **IIB (Rule10)**
GMDN Code : **37645**
UMDNS Code : **18430**

are compliant with **Annex I** of the Following Directives and Standards.

Directive:

Medical Device Directive : 93/42/EEC

Standards:

MDD :	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+A2,	EN 60627:2001,
	EN 62366:2008+A1,	EN 62220-1:2004,
	EN ISO 10993-1:2009+AC:2010,	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 RADspeed Pro ZCCE-0070BD

18. Nov. 2022 (issued date)

Kyoto, Japan (place)

 (signature)
Koichi Kataoka (full name)

General Manager, Quality Assurance Department,
Medical Systems Division,
Shimadzu Corporation