

ZCCM-0070AF

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**
Model Name : **RADspeed Pro**
Parts Number : **566-18100-01, -02, -03, -06, -11, -16, -21**
566-18100-22, -23, -26, -41, -42, -43
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,
EN 60601-1-6:2010+A1, EN 60601-2-54:2009+A1, EN 60627:2001,
EN 62366:2008, 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

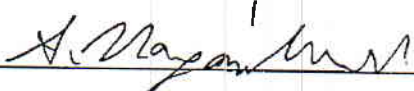
Shimadzu Europa GmbH

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-0070AU**

24, Nov. 2020 (issued date)

 (signature)
Shigeru Naganishi (full name)

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