

## 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**  
MDD Classification : **I Ib (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

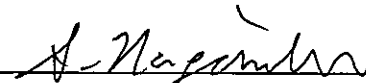
Importer/Distributor and Authorized Representative in EU

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-0070AR**

10. June 2020 (issued date)

 (signature)  
Shigeru Naganishi (full name)

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