

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 : **Radiography System**
Model Name : **Radiography System RADspeed fit**
Parts Number : **566-12700-60, 566-12700-61, 566-12700-62, 566-12700-70**
566-12700-71
MDD Classification : **IIB (Rule10)**
GMDN Code : **37645**
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+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 62304:2006+AC2008
EN 62366:2008+A1
EN 62220-1:2004
EN ISO 10993-1:2009
EN ISO 14971:2012
EN ISO 15223-1:2016
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, 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 fit ZCCE-0107H

29, June 2021 (issued date) K. Kataoka (signature)
Kyoto, Japan (place) Koichi Kataoka (full name)
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Medical Systems Division,
Shimadzu Corporation