

## 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-0107J

20, Dec. 2021 (issued date)

Kyoto, Japan (place)

 (signature)

Koichi Kataoka (full name)  
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Medical Systems Division,  
Shimadzu Corporation