



ZCCM-0107D

## CE 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 : 566-12700-01, 566-12700-11  
MDD Classification : IIb (Rule10)  
GMDN Code : 37644  
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  
EN 60601-1-2:2007  
EN 60601-1-3:2008  
EN 60601-1-6:2010  
EN 60601-2-54:2009  
EN 60627:2001  
EN 62304:2006+AC2008  
EN 62366:2008  
EN 62220-1:2004  
EN ISO 10993-1:2009  
EN ISO 14971:2012  
EN 980:2008  
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, D-90431 Nurnberg, Germany (Notified under No. 0197) as Registration No.: HD 60104281 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, F.R. 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-0107D

4, Oct. 2016 (issued date)

(signature)

Toshio Kadowaki (full name)  
General Manager, Quality Assurance Dept.  
Medical Systems Div.  
Shimadzu Corporation