



ZCCM-0101H

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 : **X-RAY TV SYSTEM**
Model Name : **X-RAY TV SYSTEM SONIALVISION G4**
Parts Number : **566-10000-11, 566-10000-12, 566-10000-13,**
566-10000-16, 566-10000-17
MDD Classification: **I Ib (Rule10)**
GMDN Code : **37679**
UMDNS Code : **16885**

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 60601-2-43:2010
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 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 60130116 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 SONIALVISION G4 ZCCE-0101H

2. Aug. 2018 (issued date)

(signature)

Toshio Kadowaki

(full name)

General Manager, Quality Assurance Dept. Medical Systems Div. Shimadzu Corporation