



Declaration of Conformity
According to EN45014



Manufacturer's Name & Address:

FUJIFILM SonoSite, Inc.
21919 30th Drive SE
Bothell, Washington 98021-3904 USA

European Authorized Representative's Name & Address:

Emergo Europe
Molenstraat 15
2513 BH, The Hague, The Netherlands

Declares that the CE-marked product(s):

Table with 3 columns: Item, Part Number(s), GMDN Code. Rows include TITAN High-Resolution Mobile Ultrasound System and various transducer models.

Complies with:

European Community Council Directive (Medical Device Directive) 93/42/EEC as amended by 2007/47/EC, Annex II, and are Class IIa devices in accordance with Annex IX, Rule 10. EC Certificate 02429 has been issued by the British Standards Institution for compliance with Annex II, section 3.2 of the European Council Directive 93/42/EEC. In addition, that said products comply with the applicable requirements of:

Conformity Assessment Certificate:

CE 02429 Full Quality Assurance Certificate first issued 13 September 1999 by BSI in respect of the design, development and manufacture of portable diagnostic ultrasound equipment, transducers and other associated accessories.

Standards Applied:

- EN60601-1: 1990, 2nd Edition including Amendment 1 and 2
EN60601-1-1: 1993
EN60601-1-2:2001

Quality Management and Quality Assurance:

- ISO 9001:2008, Quality management systems -- Requirements International Organization for Standardization
ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 13485:2012, Medical devices - Quality management systems - Requirements for regulatory purposes

February 15, 2013
Bothell, Washington USA

Ken Hansen
Director, Regulatory Affairs and Quality Systems