



Declaration of Conformity
According to ISO/IEC 17050-1



Manufacturer's Name & Address:

FUJIFILM SonoSite, Inc.
21919 30th Drive SE
Bothell, Washington 98021 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. Lists various ultrasound systems and transducers with their corresponding part numbers and GMDN codes.

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:

- EN IEC 60601-1: 2006, 3rd Edition
EN IEC 60601-2-37: 2008
EN IEC 60601-1-2: 2007
EN ISO 14971: 2012

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
EN ISO 13485:2012, Medical devices -- Quality management systems -- Requirements for regulatory purposes

February 12, 2014
Bothell, Washington USA

Ken Hansen
Director, Quality Assurance