CE 0086

Declaration of Conformity

According to ISO/IEC 17050-1

SonoSite FUJIFILM

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):

Item	Part Number(s)	GMDN Code
SonoSite EDGE Ultrasound System	P15000	40761,40762,40763,40764
Transducer, C8x/8-5	P08010	40771, 40772
Transducer, C11x/8-5	P07678	40768
Transducer, C60x/5-2	P07680	40768
Transducer, D2x/2	P05165	40768
Transducer, HFL38x/13-6	P07682	40768
Transducer, HFL50x/15-6	P07693	40768
Transducer, ICTx/8-5	P07690	40771, 40772
Transducer, L25x/13-6	P07691	40768
Transducer, L38x/10-5	P07694	40768
Transducer, L38xi/10-5	P12742	40768
Transducer, P10x/8-4	P07696	40768
Transducer, P11x/10-5	P16665	40768
Transducer, P21x/5-1	P07698	40768
Transducer, SLAx/13-6	P07699	40770
Transducer, TEEx/8-3	P05183, P05677	37891

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: 2001
- EN60601-1: 2006, 3rd Edition
- EN60601-2-37: 2001 + A1 (2004)
- EN60601-2-37: 2008
- EN60601-1-2: 2007

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

October 24, 2013
Bothell, Washington USA

Ken Hansen
Director, Regulatory Affairs and Quality Systems