Declaration of Conformity

According to ISO/IEC 17050

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	Classification	Part No.	GMDN Code
Bar Code Reader Kit	Rule 1	P07718	17220
Battery Pack	Rule 1	P07753	36534
Bracket, Single Transducer Kit	Rule 1	P08872	41143
Keyboard Tray	Rule 1	P07963	15609
Low Noise Power Supply	Rule 1	P08792, P09823	36529
PowerPack	Rule 1	P13559	17115, 36534
PowerPark Dock Module	Rule 1	P12834	37341
PowerPark Stand Module	Rule 1	P12822	37341
Triple Transducer Connect	Rule 1	P15950, P16871	39128
USB Bar Code Scanner Kit	Rule 1	P12235	17220
V Universal Stand	Rule 1	P09900, P12738	37341
Wireless Kit	Rule 1	P12240	16902
SiteLink™ Image Management System	Rule 12	P10117	40224
SonoCalc® IMT Measurement Software	Rule 12	P14699	40224
SonoSite® Workflow Solutions	Rule 12	P13321, P14047	40224

Complies with:

European Community Council Directive (Medical Device Directive) 93/42/EEC as amended by 2007/47/EC, Annex VII, and are Class I medical device accessories in accordance with Annex IX, Rule 1 and Annex IX, Rule 12. In addition, that said products comply with the applicable requirements of:

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

June 24, 2013
Bothell, Washington USA

Ken Hansen
Director, Regulatory Affairs and Quality Systems