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):

Item	Classification	Part Number(s)	GMDN Code
Battery Pack	Rule 1	P07168	36534
ECG Cable Assembly	Rule 1	P01592	31684
External 15" Flat Panel Display	Rule 1	P07076	36612
H Universal Stand	Rule 1	P12163	37341
Low Noise Power Supply	Rule 1	P01139, P03354, P06936	36529
Mini Dock	Rule 1	P03411, P05964, P10370	40811
Mobile Docking System – Enhanced (MDSe)	Rule 1	P06416	37341
Mobile Docking System – Lite	Rule 1	P04224, P08050	37341
Triple Transducer Connect Module	Rule 1	P04764	39128
SiteLink™ Image Management System with DICOM	Rule 12	P03538, P04997	40224
SonoCalc® IMT Measurement Software	Rule 12	P05337, P07876	40224

Complies with:

European Community Council Directive (Medical Device Directive) 93/42/EEC as amended by 2007/47/EC, 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: 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