CE

Declaration of Conformity

According to ISO/IEC 17050

SonoSite FUJIFILM

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):

Item	Classification	Part Number(s)	GMDN Code
Bar Code Scanner Kit	Rule 1	P14166	37035
ECG Cable and Leadwires, Lead II, EU	Rule 1	P15171	35562
Power Supply	Rule 1	P14521	40761,36545
PowerPark Dock	Rule 1	P12834	40761
PowerPark Stand Module	Rule 1	P12822	40761
X-Porte Control Panel	Rule 1	P14027	40761,40971
X-Porte Clinical Monitor	Rule 1	P14627	40761,36612
X-Porte Dock with DVR	Rule 1	P15164	40761
X-Porte TTC	Rule 1	P14644	40761

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:

- 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

November 19, 2013
Bothell, Washington USA

Ken Hansen
Director, Quality Assurance