CE

# *Declaration of Conformity*

*According to EN45014*

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 | Classification | Part Number(s) | GMDN Code |
|---|---|---|---|
| AC Power Supply | Rule 1 | P00538 | 36529 |
| Basic Stand | Rule 1 | P01708 | 37341 |
| Battery Pack | Rule 1 | P00049 | 36534 |
| CRT Stand | Rule 1 | P01881 | 37341 |
| ECG Cable | Rule 1 | P03246 | 31684 |
| ECG Cable Assembly | Rule 1 | P01592 | 31684 |
| SiteCharge® Dual Battery Charger | Rule 1 | P00552 | 17115 |
| SiteStand® Mobile Docking Station | Rule 1 | P00375, P01606, P02517 | 37341 |
| SonoCalc™ IMT Measurement Software | Rule 12 | P05337, P05349, P05960 | 40224 |
| SiteLink™ Image Management System | Rule 12 | P01370 | 40224 |
| SiteLink™ Image Management System with DICOM | Rule 12 | P04049 | 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, Second 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