



**Declaration of Conformity**  
According to EN45014

**Manufacturer's Name & Address:**

SonoSite, Inc.  
21919 - 30<sup>th</sup> Drive SE  
Bothell, Washington 98021-3904 USA

**European Compliance Representative's Name & Address:**

SonoSite, Ltd.  
European Headquarters  
Alexander House, 40A Wilbury Way, Hitchin, Herts, SG4 0AP UK

**Declares that the CE-marked product(s):**

Item	Part Number(s)	GMDN Code	Manufacturer
AC Power Supply	P01139, P03354, P06936	36529	Elpac Electronics, Inc.
Battery Pack	P02569, P07168, P09059	36534	MicroPower Electronics, Inc.
ECG Cable	P01592, P03246	31684	National Cable Molding
External 12.1" Flat Panel Display	P03053	36612	Pixelink, Inc.
External 15" Flat Panel Display	P07076	36612	National Display, Inc.
Mini Dock	P03411, P05964	40811	Celestica (Thailand), Ltd.
Mobile Docking System	P02490, P03608, P04968, P06416	37341	SonoSite, Inc.
Mobile Docking System Enhanced (MDSe)	P06416	37341	SonoSite, Inc.
Mobile Docking System – Lite	P04224	37341	Celestica (Thailand), Ltd.
SiteLink™ Image Management System	P03540	40224	SonoSite, Inc.
SiteLink™ Image Management System with DICOM	P03538, P04112, P04997	40224	SonoSite, Inc.
SonoCalc® IMT Measurement Software	P05337, P05349, P05960	40224	SonoSite, Inc.
Triple Transducer Connect Module	P03769	39128	Celestica (Thailand), Ltd.

**Complies with:**

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

**Safety:**

- EN60601-1: 1990, 2<sup>nd</sup> Edition including Amendment 1 and 2
- EN60601-1-1: 1993

**EMI / EMC:**

- EN60601-1-2:2001 (when tested as part of the ultrasound system)

**Quality Management and Quality Assurance:**

- ISO 9001:2000 Quality management systems -- Requirements International Organization for Standardization (2000)
- ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes (2003)

June 17, 2008  
Bothell, Washington USA

Daina L. Graham  
Vice-President, Regulatory Affairs and Quality Assurance