



**Declaration of Conformity**  
According to EN45014

**Manufacturer's Name:**

SonoSite, Inc.

**European Compliance Representative's Name:**

SonoSite, Ltd.

**Manufacturer's Address:**21919 30<sup>th</sup> Drive SE  
Bothell, Washington 98021-3904 USA**European Compliance Representative's Address:**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
Power Supply / Battery Charger	P01139, P06936	36529	Elpac Power Systems, Inc.
iLook <sup>®</sup> Battery Pack, 3 Cell Lithium-Ion	P01911	36534	MicroPower Electronics, Inc.
Docking Station/Charger, iLook <sup>®</sup>	P02414	37428	SonoSite, Inc.
iLook <sup>®</sup> Stand	P02647	37341	SonoSite, Inc.
iLook Auxiliary Power Cable	P02803	33051	Symmetry Electronics, Inc.
SiteLink <sup>™</sup> Image Management System	P03540	40224	SonoSite, Inc.
SiteLink <sup>™</sup> with DICOM 1.0	P04049	40224	SonoSite, Inc.

**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, Second Edition including Amendment 1 and 2
- EN60601-1-1: 1993

**EMI / EMC:**

- EN60601-1-2:2001 Second Edition

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)
- NO.169:2004, Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-vitro Diagnostic Reagents (2004)

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

August 20, 2007  
Bothell, Washington USA