

**Manufacturer's Declaration of Conformity**  
According To Australian Therapeutic Goods (Medical Devices) Regulations 2002



This is a declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian *Therapeutic Goods (Medical Devices) Regulations 2002* relating to the devices stated in following Schedule.

**Manufacturer's Name:**

SonoSite, Inc.

**Australasia Sponsor's Name:**

SonoSite Australasia, Ltd.

**Manufacturer's Address:**

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

**Australasia Sponsor's Address:**

Australasia Headquarters  
Suite 205, 14 Rodborough Road, Frenchs Forest NSW 2086 Australia

**Declares that the 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 <sup>®</sup> 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.

**Scope and Compliance:**

Each medical device accessory part number listed above 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, for each kind of medical device to which the Declaration of Conformity (not requiring assessment by Secretary) procedures have been applied the *production quality assurance procedures* have also been applied. Each kind of medical device complies with the applicable provisions of the essential principles, the classification rules before being supplied.

**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