

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 & Address:

SonoSite, Inc.
21919 - 30th Drive SE
Bothell, Washington 98021-3904 USA

Australasia Sponsor's Name & Address:

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

Declares that the product(s):

Item	Part Number(s)	GMDN Code	Manufacturer
AC Power Supply	P01139, P03354, P06936	36529	Elpac Electronics, Inc.
Battery Pack	P02569, P07168	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	SonoSite, Inc.
Mobile Docking System – Lite	P04224	37341	Celestica (Thailand), Ltd.
Mobile Docking System	P02490, P03608, P04968	37341	SonoSite, Inc.
Mobile Docking System Enhanced (MDSe)	P06416	37341	SonoSite, Inc.
SonoCalc [®] IMT Measurement Software	P05337, P05349, P05960	40224	SonoSite, Inc.
SiteLink [™] Image Management System	P03540	40224	SonoSite, Inc.
SiteLink [™] Image Management System with DICOM	P03538, P04112, P04997	40224	SonoSite, Inc.
Triple Transducer Connect Module	P03769	39128	Celestica (Thailand), Ltd.

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, 2nd 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)

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

August 20, 2007
Bothell, Washington USA