

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 the following Schedule.

Manufacturer's Name:

SonoSite, Inc.

Australasia Sponsor's Name:

SonoSite Australasia, Ltd.

Manufacturer's Address:

21919 - 30th 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
AC Power Supply	P00538	36529	Ault, Inc.
Basic Stand	P01708	37341	GCX Corporation
Battery Pack	P00049	36534	Centurion International or MicroPower Electronics
CRT Stand	P01881	37341	GCX Corporation
ECG Cable	P01592, P03246	31684	National Cable Molding
Grab And Go Carrying Case	P02724	37685	Techstyles
PC Direct Serial Cable	P02046	33051	National Cable Molding
ScanPack® Quick Access Carrier	P01313	37685	Techstyles
SiteCharge® Dual Battery Charger	P00552	17115	SelfCHARGE Inc.
SiteLink Image Management System	P01370	40224	SonoSite, Inc.
SiteLink with DICOM 1.0	P04049	40224	SonoSite, Inc.
SiteStand® Mobile Docking Station	P00375, P01606, P02517	37341	MODO, Inc., Viasystems Group, Inc. or Integrex, Inc.
SonoCalc™ IMT Measurement Software	P05337, P05349, P05960	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 (when tested as part of the ultrasound system):

- EN60601-1: 1990, Second Edition including Amendment 1 and 2
- EN60601-1-1: 1993

EMI / EMC (when tested as part of the ultrasound system):

- EN60601-1-2:2001

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

July 31, 2006
Bothell, Washington USA