

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 No.	GMDN Code	Manufacturer
AC Power Supply	P08792	36529	Mfgd by Elpac Electronics, Inc. for SonoSite, Inc.
Bar Code Reader Kit	P12235	17220	SonoSite, Inc.
Battery Pack	P07753, P09060	36534	Mfgd by MicroPower Electronics, Inc. for SonoSite, Inc.
Keyboard Tray, S Series	P07963	15609	Mfgd by Thomas Machine & Foundry for SonoSite, Inc.
Kit, Bracket, Single Transducer, S Series	P08872	41143	Mfgd by Edwin Engineering for SonoSite, Inc.
Kit, Wireless	P12240	16902	SonoSite, Inc.
SiteLink™ Image Management System	P10117	40224	SonoSite, Inc.
SonoCalc® IMT Measurement Software	P07876	40224	SonoSite, Inc.
Stand, S Series	P09223	37341	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, 2nd Edition including Amendment 1 and 2
- EN60601-1-1: 2001

EMI / EMC:

- EN60601-1-2:2007 (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

January 12, 2009
Bothell, Washington USA