

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 9, 13A Narabang Way, Belrose NSW 2085, Australia

Declares that the product(s):

Item	Part Number(s)	GMDN Code	Manufacturer
Low Noise Power Supply	P09823	36529	International Components Corporation
Battery Pack, Panasonic Cells	P09689	36534	MicroPower Electronics, Inc.
Battery Pack, Sanyo Cells	P09688	36534	MicroPower Electronics, Inc.
NanoMaxx™ Dock	P09723	40811	SonoSite, Inc.
V-Universal Stand	P12738	37341	SonoSite, Inc.
SonoCalc® IMT Measurement Software	P12807	40224	SonoSite, Inc.
SonoSite® Workflow Solutions	P13321	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 as amended by 2007/47/EC, 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 9001:2008, Quality management systems -- Requirements International Organization for Standardization
- ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes

Mary K. Moore

November 5, 2009
Bothell, Washington USA

Mary K. Moore
Vice-President, Regulatory Affairs