

Manufacturer's Declaration of Conformity

Full Quality Assurance Procedure

According To Australian Therapeutic Goods (Medical Devices) Regulations 2002



This is a declaration made in accordance with the requirements of Clause 1.8 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 - 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 No.	GMDN Code	Manufacturer
Transducer, C11x/8-5	P07678	40767	SonoSite, Inc.
Transducer, C60x/5-2	P07680	40767	SonoSite, Inc.
Transducer, HFL38x/13-6	P07682	40767	SonoSite, Inc.
Transducer, ICTx/8-5	P07690	40771, 40772	SonoSite, Inc.
Transducer, L25x/13-6	P07691	40767	SonoSite, Inc.
Transducer, L38x/10-5	P07694	40767	SonoSite, Inc.
Transducer, L52x/10-5	V00031	40767	SonoSite, Inc.
Transducer, P10x/8-4	P07696	40767	SonoSite, Inc.
Transducer, P21x/5-1	P07698	40767	SonoSite, Inc.
Transducer, SLAx/13-6	P07699	40767	SonoSite, Inc.

Scope and Compliance:

Each medical device part number listed above complies with European Community Council Directive (Medical Device Directive) 93/42/EEC, Annex II, and are Class IIa devices in accordance with Annex IX, Rule 10. EC Certificate CE 02429 has been issued by the British Standards Institution (BSI) for compliance with Annex II, section 3.2 of the European Council Directive 93/42/EEC. In addition, each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied. In addition, said devices comply with the applicable requirements of:

Safety:

- EN60601-1: 1990, 2nd Edition including Amendment 1 and 2
- EN60601-1-1: 2001
- EN60601-2-37: 2001 + A1 (2004)

EMI / EMC:

- EN60601-1-2:2007

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)

January 12, 2009
Bothell, Washington USA

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