

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 Number(s)	GMDN Code	Manufacturer
Transducer, C/8-5 Intracavitary	P03363	40762	Manufactured for SonoSite by W.L. Gore & Associates, Inc.
Transducer, C11/8-5 Neonatal	P03361, P04103, V04103	40762	Manufactured by SonoSite, Inc.
Transducer, C15/4-2 MCX	P03368, P04102, V04102	40762	Manufactured by SonoSite, Inc.
Transducer, C60/5-2	P03367, P04100, P04969, V04100, V04969	40762	Manufactured by SonoSite, Inc.
Transducer, ICT/8-5 Intracavitary	P03362, P04105, V04105	40762	Manufactured by SonoSite, Inc.
Transducer, HST/10-5	P03542, P04099, V04099	40762	Manufactured for SonoSite by Philips Ultrasound
Transducer, L38/10-5	P03366, P04101, V04101	40762	Manufactured by SonoSite, Inc.
Transducer, L25/10-5	P04791, V04791	40762	Manufactured by SonoSite, Inc.
Transducer, L52/10-5, Vet	V00028, V00029	40762	Manufactured for SonoSite by W.L. Gore & Associates, 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: 1993

EMI / EMC:

- 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)

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

April 12, 2007
Bothell, Washington USA