

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, C8/8-5	P03741	40762	Manufactured for SonoSite by W.L. Gore & Associates, Inc.
Transducer, C11/7-4 Neonatal	P01652, P01960, P02268, & P02645	40762	Manufactured by SonoSite, Inc.
Transducer, C15/4-2 MCX	P00798, P01346, P01677, P02099, P02461 P02594 & P03368	40762	Manufactured by SonoSite, Inc. or Manufactured for SonoSite by Parallel Design
Transducer, C60/5-2	P00005, P01150, P01385, P01955, P01958, P02098, P02115, P02133 & P03367	40762	Manufactured by SonoSite, Inc. or Manufactured for SonoSite by Philips Ultrasound
Transducer, HST/10-5	P02954, P03237 & P03542	40762	Manufactured for SonoSite by Philips Ultrasound
Transducer, ICT/7-4 Intracavitary	P00006, P01151, P01343, P01368, P01382, P01956, P02096, P02097, & P02450	40762	Manufactured by SonoSite, Inc. or Manufactured for SonoSite by Philips Ultrasound
Transducer, L38/10-5	P01088, P01910, P01919, P02095, P02421, P02475, & P03366	40762	Manufactured by SonoSite, Inc.
Transducer, L25/10-5	P04034	40762	Manufactured by SonoSite, Inc.
Transducer, L52/10-5	V00018, 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:

- | | |
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| • EN60601-1: 1990, 2 nd Edition including Amendment 1 and 2 | • EN60601-1-1: 1993 |
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EMI / EMC:

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| • EN60601-1-2:2001 | • RTCA/DO160D:1997, Section 21.0, Category B |
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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

April 12, 2007
 Bothell, Washington USA