

# 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 & Address:

SonoSite, Inc.  
21919 - 30<sup>th</sup> 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
SonoSite S Series™ Ultrasound System	P09041, P09417	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-Cath™ Ultrasound System	P08778	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-FAST™ Ultrasound System	P07578	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-GYN™ Ultrasound System	P11991	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-ICU™ Ultrasound System	P07577	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-MSK™ Ultrasound System	P07579	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-Nerve™ Ultrasound System	P07576	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-VetMed™ Ultrasound System	P11995	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-Women's Health™ Ultrasound System	P11993	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.

### Complies with:

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, 2<sup>nd</sup> Edition including Amendment 1 and 2
- EN60601-1-1: 2001
- EN60601-2-37: 2001 + A1 (2004)

### EMI / EMC:

- EN60601-1-2:2007

### Supplementary Information:

Included are the following Accessories and OEM Products:

#### Accessories:

AC Power Supply  
Bar Code Reader Kit  
Basket  
Battery Pack  
Biopsy/Needle Guides  
Bracket, Single Transducer  
Keyboard Tray  
SiteLink Image Management System  
SonoCalc® IMT  
Stand  
Transducer Bracket Kit  
Wireless Kit

#### Transducers:

C11x/8-5 Transducer  
C60x/5-2 Transducer  
HFL38x/13-6 Transducer  
ICTx/8-5 Transducer  
L25x/13-6 Transducer  
L38x/10-5 Transducer  
L52x/10-5 Transducer  
P10x/8-4 Transducer  
P21x/5-1 Transducer  
SLAx/13-6 Transducer

#### OEM Products:

Aquasonic 100 Acoustic Gel  
ATP Electronics, Memory, USB, 2GB  
CIVCO, Transducer covers  
DSI, Keyboard, USB, KB-ASK-3100U-US  
Sony, Black and White Video Printer, UP897MD  
Sony, DVD Recorder, DVO-1000MD  
Symbol, Bar Code Scanner, DS6707-SR2000ZZR

### 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