

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 - 30th 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 Number(s)	GMDN Code	Manufacturer
MicroMaxx [®] hand-carried ultrasound system	P05261, P05262, P05263, P05264, P05265, P05361, P05670, P06418, P06468, P06469, P06470, P06471, P06472, P06473, P06996, P07071, P07099, P07100, P07101, P07102, P07103, P07104, P07105, P08840, V06468, V06469, V06470, V06471, V06472, V06473, V07099, V07100, V07101, V07102, V07103, V07104, V08840	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, 2nd Edition including Amendment 1 and 2
- EN60601-1-1: 2001
- EN60601-2-37: 2001 + A1 (2004)

EMI / EMC:

- EN60601-1-2:2001

Supplementary Information:

Included are the following Accessories and OEM Products:

Accessories:

AC Power Supply
Battery Pack
Biopsy/Needle Guides
ECG Cable, ECG Adapter
External 12.1" Flat Panel Display
Mini Dock
Mobile Docking System, Mobile Docking System Enhanced, Mobile Docking System - Lite
Protective Connector Box (for LAP, SLA and SLT transducers)
SiteLink Image Management System
SonoCalc[®] IMT (embedded and standalone version)
SonoSite C8e/8-5 Transducer
SonoSite C11e/8-5 Transducer

SonoSite C60e/5-2 Transducer
SonoSite D2/2 Transducer
SonoSite HFL38e/13-6 Transducer
SonoSite ICT/8-5 Transducer
SonoSite LAP/12-5 Transducer
SonoSite L25e/13-6 Transducer
SonoSite L38e/10-5 Transducer
SonoSite L52e/10-5 Transducer
SonoSite P10/8-4 Transducer
SonoSite P17/5-1 Transducer
SonoSite SLA/13-6 Transducer
SonoSite SLT/10-5 Transducer
SonoSite TEE/8-3 Transducer
Triple Transducer Connect Module
Wireless Upgrade Kit

OEM Products:

Aquasonic 100 Acoustic Gel

CIVCO, Transducer covers
Compact Flash Card
Linemaster SP-997-216 Footswitch
Mitsubishi, VCR, NTSC, MD-3000U
Mitsubishi, VCR, PAL, MD-3000E
National Display, 15" Flat Panel Display
Panasonic, DVD Recorder, LQ-MD800
Sony, Black and White Video Printer, UP897MD
Sony, Color Video Printer, UP-21MD
Sony, Digital Video Recorder, GV-D800
Sony, DVD Recorder, DVO-1000MD
Sony, External color monitor, PVM14M2-MDU
Symbol, Bar Code Scanner, DS6707-SR2000ZZR
Toroid Corp. Isolation Transformer

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

December 19, 2007
Bothell, Washington USA