

STATE OF WASHINGTON            )  
  )  
COUNTY OF SNOHOMISH        )        ss.

I certify that the attached certificate is a true and correct copy of a document in the possession of SonoSite, Inc. as of this date.

Dated this 12 day of May, 2009.



Jessica R Schram  
Jessica R Schram

Printed Name  
Notary Public in and for the State of Washington  
My appointment expires 4-19-13

*Manufacturer's Declaration of Conformity*  
According To Australian Therapeutic Goods (Medical Devices) Regulations 2002



This is a declaration made in accordance with the requirements of Clause 6.6 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 9, 13A Narabang Way, Belrose NSW 2085 Australia

**Declares that the product(s):**

Item	Part Number(s)	GMDN Code	Manufacturer
AC Power Supply	P01139, P03354, P06936	36529	Elpac Electronics, Inc.
Bar Code Reader Kit	P07718	17220	SonoSite, Inc.
Battery Pack	P02569, P07168, P09059	36534	MicroPower Electronics, Inc.
ECG Cable	P01592, P03241, P04448	31684	National Cable Molding
ECG Adaptor Kit	P07182	31684	SonoSite, Inc.
External 12.1" Flat Panel Display	P03053	36612	Pixelink, Inc.
External 15" Flat Panel Display	P07076	36612	National Display, Inc.
Mini Dock	P03411, P05964, P10370	40811	Celestica (Singapore), Ltd.
Mobile Docking System	P03608, P04968, P06416, P010361	37341	Allied Panels
Mobile Docking System – Lite	P04224, P08050	37341	Celestica (Singapore), Ltd.
Protective Connector Box (for LAP, SLA and SLT transducers)	P05829	42479	SonoSite, Inc.
SiteLink™ Image Management System	P05346, P05671, P05959, P06804, P07243, P07638, P11922	40224	SonoSite, Inc.
Wireless Upgrade Kit	P06041, P06641, P06869	36702	SonoSite, Inc.
SonoCalc® IMT Measurement Software	P05337, P05349, P05960, P07241, P07876	40224	SonoSite, Inc.
Triple Transducer Connect Module	P03769, P04764	39128	Celestica (Singapore), Ltd.

**Scope and Compliance:**

Each medical device accessory part number listed above complies with European Community Council Directive (Medical Device Directive) 93/42/EEC, VII, and are Class I medical device accessories in accordance with Annex IX, Rule 12. In addition, for each kind of medical device to which the Declaration of Conformity (not requiring assessment by Secretary) procedures have been applied the *production quality assurance procedures* have also been applied. Each kind of medical device complies with the applicable provisions of the essential principles, the classification rules before being supplied.

**Safety:**

- EN60601-1: 1990, 2<sup>nd</sup> Edition including Amendment 1 and 2
- EN60601-1-1: 2001

**EMI / EMC:**

- EN60601-1-2:2007 (when tested as part of the ultrasound system)

**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)

May 12, 2009  
Bothell, Washington USA

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