

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 5th day of November, 2009.



Jessica R Schram

Jessica R Schram

Printed Name
Notary Public in and for the State of Washington
My appointment expires 4-19-2013

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 - 30th 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	P08792, P09823	36529	Elpac Electronics, Inc.
Bar Code Reader Kit	P07718, P12235	17220	SonoSite, Inc.
Battery Pack	P07168	36534	MicroPower Electronics, Inc.
ECG Cable	P01592, P03241	31684	Tyco
ECG Adaptor Kit	P07182	31684	SonoSite, Inc.
H Universal Stand	P12163	37341	Celestica (Singapore) Ltd.
Kit, Wireless	P12240	16902	SonoSite, Inc.
Mini Dock	P07677, P08788, P10400, P10401	40811	Celestica (Singapore), Ltd.
Mobile Docking System	P08055, P10410	37341	Allied Panels
Mobile Docking System – Lite II	P08800	37341	Celestica (Singapore), Ltd.
SiteLink™ Image Management System	P08152, P10117	40224	SonoSite, Inc.
SonoCalc® IMT Measurement Software	P07241, P07876	40224	SonoSite, Inc.
SonoSite® Workflow Solutions	P13321	40224	SonoSite, Inc.
Triple Transducer Connect Module	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 as amended by 2007/47/EC, 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, 2nd 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 9001:2008, Quality management systems -- Requirements International Organization for Standardization
- ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes

Mary K. Moore

November 5, 2009
Bothell, Washington USA

Mary K. Moore
Vice-President, Regulatory Affairs