

STATE OF WASHINGTON)
) ss.
COUNTY OF SNOHOMISH)

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 28th day of December, 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
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, C11x/8-5	P07678, V07678	40767	SonoSite, Inc.
Transducer, C60x/5-2	P07680, V07680	40767	SonoSite, Inc.
Transducer, D2x/2	P05165	40767	SonoSite, Inc.
Transducer, P10x/8-4 MHz	P07696, V07696	40767	SonoSite, Inc.
Transducer, HFL38x/13-6	P07682, V07682	40767	SonoSite, Inc.
Transducer, HFL50x/15-6	P07693	40767	SonoSite, Inc.
Transducer, ICTx/8-5	P07690, V07690	40771, 40772	SonoSite, Inc.
Transducer, L25x/13-6	P07691, V07691	40767	SonoSite, Inc.
Transducer, L38x/10-5	P07694, V07694	40767	SonoSite, Inc.
Transducer, L38xi/10-5	P12742	40767	SonoSite, Inc.
Transducer, L52x/10-5	V00031	40767	SonoSite, Inc.
Transducer, P21x/5-1, Phased Array	P07698, V07698	40767	SonoSite, Inc.
Transducer, SLAx/13-6 MHz	P07699	40770	SonoSite, Inc.
Transducer, TEE _x /8-3 MHz	P05183	37891	GE Vingmed Ultrasound A/S

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:

- EN60601-1: 1990, 2nd Edition including Amendment 1 and 2
- EN60601-1-1: 2001
- EN60601-2-37: 2001 + A1 (2004)

EMI / EMC:

- EN60601-1-2:2007

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

December 28, 2009
Bothell, Washington USA

Mary K. Moore
Vice-President, Regulatory Affairs