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:

FUJIFILM SonoSite, Inc.
21919 30th Drive SE
Bothell, Washington 98021-3904 USA

Australasia Sponsor's Name & Address:

FUJIFILM SonoSite Australasia Pty, Ltd.
Suite 9, 13A Narabang Way
Belrose, NSW 2085, Australia

Declares that the product(s):

Item	Part No.	GMDN Code
SonoSite S Series™ Ultrasound System	P09041, P09417, P12057	40761, 40762, 40763, 40764
SonoSite S-Cath™ Ultrasound System	P08778	40761, 40762, 40763, 40764
SonoSite S-FAST™ Ultrasound System	P07578	40761, 40762, 40763, 40764
SonoSite S-GYN™ Ultrasound System	P11991	40761, 40762, 40763, 40764
SonoSite S-ICU™ Ultrasound System	P07577	40761, 40762, 40763, 40764
SonoSite S-MSK™ Ultrasound System	P07579	40761, 40762, 40763, 40764
SonoSite S-Nerve™ Ultrasound System	P07576	40761, 40762, 40763, 40764
SonoSite S-VetMed™ Ultrasound System	P11995	40761, 40762, 40763, 40764
SonoSite S-Women's Health™ Ultrasound System	P11993	40761, 40762, 40763, 40764
Transducer, C8x/8-5	P08010	40771, 40772
Transducer, C11x/8-5	P07678	40767, 40768
Transducer, C60x/5-2	P07680	40767, 40768
Transducer, HFL38x/13-6	P07682	40767, 40768
Transducer, HFL50x/15-6	P07693	40767, 40768
Transducer, ICTx/8-5	P07690	40771, 40772
Transducer, L25x/13-6	P07691	40767, 40768
Transducer, L38x/10-5	P07694	40767, 40768
Transducer, L38xi/10-5	P12742	40767, 40768
Transducer, P10x/8-4	P07696	40767, 40768
Transducer, P11x/10-5	P16665	40767, 40768
Transducer, P21x/5-1	P07698	40767, 40768
Transducer, SLAx/13-6	P07699	40770
Transducer, TEEx/8-3	P05677	37891

Scope and Compliance:

Each medical device part number listed above complies with the Therapeutic Good (Medical Devices) Regulations 2002 and are Class IIa devices in accordance with Schedule 2, Part 1, Rule 4.3 (2) (a) as demonstrated in accordance with Schedule 3, Part 1. 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.

Conformity Assessment Certificate:

CE 02429 Full Quality Assurance Certificate first issued 13 September 1999 by BSI in respect of the design, development and manufacture of portable diagnostic ultrasound equipment, transducers and other associated accessories.

Standards Applied:

- EN60601-1: 1990, 2nd Edition including Amendment 1 and 2
- EN60601-1-1: 2001
- EN60601-1: 2006, 3rd Edition
- EN60601-2-37: 2001 + A1 (2004)
- EN60601-2-37: 2008
- EN60601-1-2: 2007

For additional information regarding this Declaration, please contact FUJIFILM SonoSite, Inc., your local SonoSite affiliate, or the SonoSite Australasia Representative.

Declaration of Conformity

According to EN45014

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
- EN ISO 13485:2012, Medical devices – Quality management systems – Requirements for regulatory purposes

July 30, 2013
Bothell, Washington USA

Ken Hansen
Director, Regulatory Affairs and Quality Systems