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 Number(s)	GMDN Code
X-Porte Ultrasound System and Stand	P17860, P17870	40761,40762,40763,40764,40971
X-Porte Ultrasound System (engine)	P16055	40761,40762,40763,40764
Transducer, C60xp/5-2	P14561	40768
Transducer, HFL50xp/15-6	P14567	40768
Transducer, HSL25xp/13-6 MHz	P18657	40768
Transducer, ICTxp/9-5	P14562	40771, 40772
Transducer, L25xp/13-6	P14566	40768
Transducer, L38xp/10-5	P14565	40768
Transducer, P21xp/5-1	P14563	40768

Scope and Compliance:

Each medical device part number listed above complies with the Therapeutic Goods (Medical Devices) Regulations 2002 and are Class IIa medical 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:

- EN IEC 60601-1: 2006, 3rd Edition
- EN IEC 60601-2-37: 2008
- EN IEC 60601-1-2: 2007
- EN ISO 14971: 2012

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

February 12, 2014
Bothell, Washington USA

Ken Hansen
Director, Quality Assurance