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 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:

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	Classification	Part Number(s)	GMDN Code
Bar Code Reader Kit	Class 1, Rule 2.1	P07718	17220
Battery Pack	Class 1, Rule 2.1	P07168	36534
ECG Cable Assembly	Class 1, Rule 2.1	P01592, P03241	31684
H Universal Stand	Class 1, Rule 2.1	P12163	37341
Low Noise Power Supply	Class 1, Rule 2.1	P08792, P09823	36529
Mini Dock	Class 1, Rule 2.1	P07677, P08788, P10400, P10401	40811
PowerPack	Class 1, Rule 2.1	P13559	17115, 36534
PowerPark Dock Module	Class 1, Rule 2.1	P12834	37341
PowerPark Stand Module	Class 1, Rule 2.1	P12822	37341
Triple Transducer Connect Module	Class 1, Rule 2.1	P04764	39128
USB Bar Code Scanner Kit	Class 1, Rule 2.1	P12235	17220
Wireless Kit	Class 1, Rule 2.1	P12240	16902
SiteLink™ Image Management System	Class 1, Rule 4.1	P10117	40224
SonoCalc® IMT Measurement Software	Class 1, Rule 4.1	P14699	40224
SonoSite® Workflow Solutions	Class 1, Rule 4.1	P13321, P14047	40224

Scope and Compliance:

Each medical device part number listed above complies with the Therapeutic Goods (Medical Devices) Regulations 2002 and are Class I medical devices in accordance with Schedule 2, Part 1, Rule 2.1 and Rule 4.1, as demonstrated in accordance Schedule 3, Part 6, Clause 6.6 and 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.

Standard 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

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 29, 2013
Bothell, Washington USA

Ken Hansen
Director, Regulatory Affairs and Quality Systems

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