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
ECG Adaptor Kit	Class 1, Rule 2.1	P07182	31684
External 15" Flat Panel Display	Class 1, Rule 2.1	P07076	36612
Footswitch Kit	Class 1, Rule 2.1	P06865	36336
H Universal Stand	Class 1, Rule 2.1	P12163	37341
Low Noise Power Supply	Class 1, Rule 2.1	P01139, P06936, P09823	36529
Mini Dock	Class 1, Rule 2.1	P05964, P10370	40811
Mobile Docking System – Enhanced (MDSe)	Class 1, Rule 2.1	P10361	37341
Mobile Docking System – Lite	Class 1, Rule 2.1	P04224	37341
PowerPark	Class 1, Rule 2.1	P12834	37341
Protective Connector Box	Class 1, Rule 2.1	P05829	42479
Triple Transducer Connect Module	Class 1, Rule 2.1	P04764	39128
Wireless Upgrade Kit	Class 1, Rule 2.1	P06869	36702
SiteLink™ Image Management System	Class 1, Rule 4.1	P05346, P07638, P11922	40224
SonoCalc® IMT Measurement Software	Class 1, Rule 4.1	P05337, P07241, P14699	40224
SonoSite® Workflow Solutions	Class 1, Rule 4.1	P13321	40224

Scope and Compliance:

Each medical device accessory 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.

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

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

March 07, 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.