

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 No.	GMDN Code
Bar Code Reader Kit	Class 1, Rule 2.1	P07718	17220
Battery Pack	Class 1, Rule 2.1	P07753	36534
Bracket, Single Transducer Kit	Class 1, Rule 2.1	P08872	41143
Keyboard Tray	Class 1, Rule 2.1	P07963	15609
Low Noise Power Supply	Class 1, Rule 2.1	P08792, P09823	36529
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
USB Bar Code Scanner Kit	Class 1, Rule 2.1	P12235	17220
V Universal Stand	Class 1, Rule 2.1	P09900, P12738	37341
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.

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
- 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