

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
Battery Pack	Class 1, Rule 2.1	P07168	36534
ECG Cable Assembly	Class 1, Rule 2.1	P01592	31684
External 15" Flat Panel Display	Class 1, Rule 2.1	P07076	36612
H Universal Stand	Class 1, Rule 2.1	P12163	37341
Low Noise Power Supply	Class 1, Rule 2.1	P01139, P03354, P06936	36529
Mini Dock	Class 1, Rule 2.1	P03411, P05964, P10370	40811
Mobile Docking System – Enhanced (MDS _e)	Class 1, Rule 2.1	P06416	37341
Mobile Docking System – Lite	Class 1, Rule 2.1	P04224, P08050	37341
Triple Transducer Connect Module	Class 1, Rule 2.1	P04764	39128
SiteLink™ Image Management System with DICOM	Class 1, Rule 4.1	P03538, P04997	40224
SonoCalc® IMT Measurement Software	Class 1, Rule 4.1	P05337, P07876	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.

Standards Applied:

- EN60601-1: 1990, 2nd Edition including Amendment 1 and 2
- EN60601-1-1: 1993
- EN60601-1-2:2001 (when tested as part of the ultrasound system)

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 12, 2013
Bothell, Washington USA

Ken Hansen
Director, Regulatory Affairs and Quality Systems