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
SonoSite® 180™ Hand-Carried Ultrasound System	P00007	40761, 40762, 40763, 40764
SonoHeart™ Personal Hand-Carried Ultrasound Sytem	P00929	40761, 40762, 40763, 40764
SonoSite® 180™ HF Hand-Carried Ultrasound System and SonoHeart™ HF Hand-Carried Ultrasound System	P01103, P01163, P01424	40761, 40762, 40763, 40764
SonoSite® 180PLUS™, SonoHeart™ PLUS, and SonoHeart™ ELITE Hand-Carried Ultrasound System	P01576, P02030, P02031, P02462, P02463, P02464, P02521, P02522, P04247, P04248, P04249, P04250, P04251, P04252, P04253, P04254, P04255, P04256, P04257, P04258	40761, 40762, 40763, 40764
Transducer, C8/8-5	P03741	40771, 40772
Transducer, C11/7-4	P01652, P01960, P02268, P02645	40767, 40768
Transducer, C15/4-2	P00798, P01346, P01677, P02099, P02461 P02594, P03368	40767, 40768
Transducer, C60/5-2	P00005, P01150, P01385, P02098, P02115, P02133, P03367	40767, 40768
Transducer, HST/10-5	P02954, P03237, P03542	40770
Transducer, ICT/7-4	P00006, P01151, P01343, P01368, P01382, P01956, P02096, P02097, P02450	40771, 40772
Transducer, L38/10-5	P01088, P01910, P01919, P02095, P02475, P03366	40767, 40768
Transducer, L25/10-5	P04034	40767, 40768

Complies with:

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:

- EN60601-1: 1990, 2nd Edition including Amendment 1 and 2
- EN60601-1-1: 1993
- EN60601-1-2:2001

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

April 2, 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.