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
L25 Bracket Only Kit	Class 1, Rule 2.1	P03434	58248
L25 Needle Guide/ Cover Kit (18 Gauge)	Class 1, Rule 2.1	P12920	45018
L25 Needle Guide/ Cover Kit (21 Gauge)	Class 1, Rule 2.1	P12922	45018
L25 Needle Guide/ Cover Kit (22 Gauge)	Class 1, Rule 2.1	P12924	45018

Scope and Compliance:

Each medical device accessory part number listed above complies with the Therapeutic Goods (Medical Devices) Regulations 2002 and are Class I sterile* 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:

- ISO 10993-01, Biological Evaluation of Medical Devices
- ISO 11135-1, ETO Validation and Routine Control*
- AS ISO 11737-1, Sterilization of Medical Devices – Part 1(Bioburden)*
- EN ISO 11607, Packaging for Terminally Sterilized Medical Devices*
- AS EN 556-1, Requirements for Medical Devices to be Designated "STERILE"

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

Supplementary Information:

The L25 Bracket and L25 Needle Guide Starter Kits are manufactured for FUJIFILM SonoSite, Inc. by the designated manufacturer. The sterilizer* for the L25 Needle Guide Starter Kits is also designated:

Contract Manufacturer
CIVCO Medical Instruments Co., Inc
102 First Street South
Kalona, IA 52247 USA

Sterilizer
Cosmed Group, Inc.
1160 Northpoint Blvd.
Waukegan, IL 60085 USA

** Not applicable to P03434. Device is not sterile.*

March 12, 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.