

*Manufacturer's Declaration of Conformity*  
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:**

SonoSite, Inc.

**Australasia Sponsor's Name:**

SonoSite Australasia, Ltd.

**Manufacturer's Address:**

21919 - 30<sup>th</sup> Drive SE  
Bothell, Washington 98021-3904 USA

**Australasia Sponsor's Address:**

Australasia Headquarters  
Suite 205, 14 Rodborough Road, Frenchs Forest NSW 2086 Australia

**Declares that the product(s):**

Item	Part Number(s)	GMDN Code	Manufacturer
L25 Bracket Only Kit	P03122	10401	Manufactured for SonoSite, Inc. by CIVCO Medical Instruments Company
L25 Needle Guide/ Cover Kit (21Gauge)	P03123	10401	Manufactured for SonoSite, Inc. by CIVCO Medical Instruments Company. Sterilized by Cosmed Group, Inc.
L25 Needle Guide/Cover Kit (18 Gauge)	P03907	10401	Manufactured for SonoSite, Inc. by CIVCO Medical Instruments Company. Sterilized by Cosmed Group, Inc.
L25 Needle Guide/ Cover Kit (22 Gauge)	P03908	10401	Manufactured for SonoSite, Inc. by CIVCO Medical Instruments Company. Sterilized by Cosmed Group, Inc.
L25 Needle Guide/ Cover Kit (21 Gauge)	P04053	10401	Manufactured for SonoSite, Inc. by CIVCO Medical Instruments Company. Sterilized by Cosmed Group, Inc.

**Scope and Compliance:**

Each medical device accessory part number listed above complies with European Community Council Directive (Medical Device Directive) 93/42/EEC, Annex V, and are Class I sterile\* devices in accordance with Annex IX, Rule 1. EC Certificate 72783 has been issued by the British Standards Institution (BSI) for compliance with Annex V, section 3.2 of the European Council Directive 93/42/EEC. For each kind of medical device that is supplied sterile and to which the Conformity Assessment Procedures (not requiring assessment by Secretary) have been applied the Production Quality Assurance Procedures have also been applied. Each kind of medical device complies with the applicable provisions of the essential principles and the classification rules before being supplied. In addition, that said products comply with the applicable requirements of:

**Safety:**

- ISO 10993-01, Biological Evaluation of Medical Devices
- EN 550, ISO 11153, ETO Validation and Routine Control\*
- ANSI/AAMI/ISO, Sterilization of Medical Devices – Part 1 (Bioburden)\*
- ANSI/AAMI 11607, Packaging for Terminally Sterilized Medical Devices\*
- ISTA Project 2A, Pre-Shipment Procedure

**Quality Management and Quality Assurance:**

- ISO 9001:2000 Quality management systems -- Requirements International Organization for Standardization (2000)
- ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes (2003)
- NO.169:2004, Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-vitro Diagnostic Reagents (2004)

**Supplementary Information:**

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

**Contract Manufacturer**

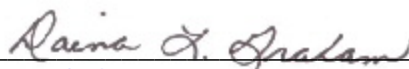
CIVCO Medical Instruments Co Inc  
102 First Street South  
Kalona, Iowa USA 52246

**Sterilizer**

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

\* Not applicable to P03122. Device is not sterile.

January 16, 2006  
Bothell, Washington USA

  
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Daina L. Graham  
Vice-President, Regulatory Affairs and Quality Assurance