



Declaration of Conformity
According to EN45014



Manufacturer's Name & Address:

FUJIFILM SonoSite, Inc.
21919 30th Drive SE
Bothell, Washington 98021-3904 USA

European Authorized Representative's Name & Address:

Emergo Europe
Molenstraat 15
2513 BH, The Hague, The Netherlands

Declares that the CE-marked product(s):

Table with 4 columns: Item, Classification, Part Number(s), GMDN Code. Rows include L25 Bracket Only Kit, L25 Needle Guide/ Cover Kit (18 Gauge), L25 Needle Guide/ Cover Kit (21 Gauge), L25 Needle Guide/ Cover Kit (22 Gauge).

Complies with:

European Community Council Directive (Medical Device Directive) 93/42/EEC as amended by 2007/47/EC, Annex VII, and are Class I sterile\* devices in accordance with Annex IX, Rule 1. In addition, that said products comply with the applicable requirements of:

Standards Applied:

- EN ISO 10993-01, Biological Evaluation of Medical Devices
EN ISO 11135-1, ETO Validation and Routine Control\*
EN ISO 11737-1, Sterilization of Medical Devices - Part 1 (Bioburden)\*
EN ISO 11607, Packaging for Terminally Sterilized Medical Devices\*
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.

February 21, 2013
Bothell, Washington USA

Ken Hansen
Director, Regulatory Affairs and Quality Systems