

STATE OF WASHINGTON)
) ss.
COUNTY OF SNOHOMISH)

I certify that the attached certificate is a true and correct copy of a document in the possession of SonoSite, Inc. as of this date.

Dated this 28th day of December, 2009.



Jessica R Schram

Jessica R Schram

Printed Name
Notary Public in and for the State of Washington
My appointment expires 4-19-2013

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:

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

Australasia Sponsor's Name & Address:

SonoSite Australasia, Ltd.
Australasia Headquarters
Suite 9, 13A Narabang Way, Belrose, NSW 2085, Australia

Declares that the product(s):

Item	Part Number(s)	GMDN Code	Manufacturer
SonoSite M-Turbo™ ultrasound system	P08189, P08241, V08189	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite M-OB/GYN Office™ ultrasound system	P08189	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite M-MSK™ ultrasound system	P08189	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.

Complies with:

Each medical device part number listed above complies with European Community Council Directive (Medical Device Directive) 93/42/EEC, Annex II, and are Class IIa devices in accordance with Annex IX, Rule 10. EC Certificate CE 02429 has been issued by the British Standards Institution (BSI) for compliance with Annex II, section 3.2 of the European Council Directive 93/42/EEC. 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. In addition, said devices comply with the applicable requirements of:

Safety:

- EN60601-1: 1990, 2nd Edition including Amendment 1 and 2
- EN60601-1-1: 2001
- EN60601-2-37: 2001 + A1 (2004)

EMI / EMC:

- EN60601-1-2:2007

Supplementary Information:

Included are the following Accessories and OEM Products:

Accessories:

AC Power Supply
Battery Pack
Biopsy/Needle Guides
ECG Cable, ECG Adapter
H Universal Stand
Mini Dock
Mobile Docking System
Mobile Docking System – Lite II
SiteLink Image Management System
SonoCalc® IMT
C11x/8-5 Transducer
C60x/5-2 Transducer
D2x/2 MHz Transducer
HFL38x/13-6 Transducer

ICTx/8-5 Transducer
L25x/13-6 Transducer
L38x/10-5 Transducer
L38xi/10-5 Transducer
L52x/10-5 Transducer
P10x/8-4 Transducer
P21x/5-1 Transducer
SLAx/13-6 MHz Transducer
SonoSite Workflow Solutions
TEEx/8-3 Transducer
Triple Transducer Connect Module

OEM Products:

Aquasonic 100 Acoustic Gel
CIVCO, Transducer covers
Linemaster SP-997-216 Footswitch

National Display, 15" Flat Panel Display
Panasonic, DVD Recorder, LQ-MD800
Sony, Black and White Video Printer, UP897MD
Sony, Color Video Printer, UP-21MD
Sony, Digital Video Recorder, GV-D800
Sony, DVD Recorder, DVO-1000MD
Sony, External color monitor, PVM14M2-MDU
SparkLAN, USB WIRELESS DONGLE,
54MBPS, 802.11G, WL-685R
Symbol, Bar Code Scanner, DS6707-
SR2000ZZR
Symbol, Bar Code Scanner, USB, LS2208-
SR20007R-UR
Toroid Corp. Isolation Transformer

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

December 28, 2009
Bothell, Washington USA

Mary K. Moore
Vice-President, Regulatory Affairs