



Declaration of Conformity
According to EN45014

**Manufacturer's Name & Address:**

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

European Compliance Representative's Name & Address:

SonoSite, Ltd.
European Headquarters
Alexander House, 40A Wilbury Way, Hitchin, Herts, SG4 0AP UK

Declares that the CE-marked product(s):

Item	Part Number(s)	GMDN Code	Manufacturer
SonoSite S Series™ Ultrasound System	P09041	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-Nerve™ Ultrasound System	P07576	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-FAST™ Ultrasound System	P07578	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-ICU™ Ultrasound System	P07577	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-Cath™ Ultrasound System	P08778	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
SonoSite S-MSK™ Ultrasound System	P07579	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.

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 02429 has been issued by the British Standards Institution for compliance with Annex II, section 3.2 of the European Council Directive 93/42/EEC. In addition, that said products comply with the applicable requirements of:

Safety:

- | | |
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| <ul style="list-style-type: none"> EN60601-1: 1990, 2nd Edition including Amendment 1 and 2 EN60601-1-1: 2001 | <ul style="list-style-type: none"> EN60601-2-37: 2001 + A1 (2004) |
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EMI / EMC:

- EN60601-1-2:2001

Supplementary Information:

Included are the following Accessories and OEM Products:

Accessories:

AC Power Supply
Basket
Battery Pack
Biopsy/Needle Guides
Bracket, Single Transducer
Keyboard Tray
Stand

Transducers:

C11x/8-5 Transducer
C60x/5-2 Transducer
HFL38x/13-6 Transducer
ICTx/8-5 Transducer
L25x/13-6 Transducer
L38x/10-5 Transducer
P21x/5-1 Transducer

OEM Products:

Aquasonic 100 Acoustic Gel
ATP Electronics, Memory, USB, 2GB
CIVCO, Transducer covers
DSI, Keyboard, USB, KB-ASK-3100U-US
Sony, Black and White Video Printer, UP897MD
Sony, DVD Recorder, DVO-1000MD
Symbol, Bar Code Scanner, DS6707-SR20007ZZR

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)

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

March 10, 2008
Bothell, Washington USA