



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
MicroMaxx® hand-carried ultrasound system	P05261, P05262, P05263, P05264, P05265, P05361, P05670, P06418, P06468, P06469, P06470, P06471, P06472, P06473, P06996, P07071, P07099, P07100, P07101, P07102, P07103, P07104, P07105, P08840, V06468, V06469, V06470, V06471, V06472, V06473, V07099, V07100, V07101, V07102, V07103, V07104, V08840	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:

- 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
- External 12.1" Flat Panel Display
- Mini Dock
- Mobile Docking System, Mobile Docking System Enhanced, Mobile Docking System - Lite
- Protective Connector Box (for LAP, SLA and SLT transducers)
- SiteLink Image Management System
- SonoCalc® IMT (embedded and standalone versions)
- SonoSite C8e/8-5 Transducer
- SonoSite C11e/8-5 Transducer
- SonoSite C60e/5-2 Transducer

- SonoSite D2/2 Transducer
- SonoSite HFL38e/13-6 Transducer
- SonoSite ICT/8-5 Transducer
- SonoSite LAP/12-5 Transducer
- SonoSite L38e/10-5 Transducer
- SonoSite L25e/13-6 Transducer
- SonoSite L52e/10-5 Transducer
- SonoSite P10/8-4 Transducer
- SonoSite P17/5-1 Transducer
- SonoSite SLA/13-6 Transducer
- SonoSite SLT/10-5 Transducer
- SonoSite TEE/8-3 Transducer
- Triple Transducer Connect Module
- Wireless Upgrade Kit

OEM Products:

- Aquasonic 100 Acoustic Gel
- CIVCO, Transducer covers
- Compact Flash Card
- Linemaster SP-997-216 Footswitch
- Mitsubishi, VCR, NTSC, MD-3000U
- Mitsubishi, VCR, PAL, MD-3000E
- 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
- Symbol, Bar Code Scanner, DS6707-SR2000ZZR
- Toroid Corp. Isolation Transformer

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

August 28, 2008
Bothell, Washington USA