CE 0086

Declaration of Conformity

According to EN45014

SonoSite

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:

- EN60601-1-2:2001

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-SR20007ZZR
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)

December 19, 2007
Bothell, Washington USA

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

For additional information regarding this Declaration, please contact SonoSite, Inc., your local SonoSite affiliate, or the SonoSite European Representative.