



*Declaration of Conformity*  
According to EN45014



**Manufacturer's Name:**

SonoSite, Inc.

**European Compliance Representative's Name:**

SonoSite, Ltd.

**Manufacturer's Address:**

21919 - 30<sup>th</sup> Drive SE  
Bothell, Washington 98021-3904 USA

**European Compliance Representative's Address:**

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

**Declares that the CE-marked product(s):**

Item	Part Number(s)	Manufacturer
MicroMaxx™ hand-carried ultrasound system	P05261, P05262, P05263, P05264, P05265, P05361, P05670, P06468, P06469, P06470, P06471, P06472, P06473, V06468, V06469, V06470, V06471, V06472, V06473	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:**

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

**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  
External 12.1" Flat Panel Display  
Mini Dock  
Mobile Docking System, Mobile Docking System Enhanced, Mobile Docking System - Lite  
SiteLink Image Management System  
SonoCalc™ IMT (embedded and standalone versions)  
SonoSite C60e/5-2 Transducer  
SonoSite HFL38e/13-6 Transducer  
SonoSite ICT/8-5 Transducer  
SonoSite L38e/10-5 Transducer  
SonoSite L25e/13-6 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

**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  
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, External color monitor, PVM14M2-MDU  
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

July 31, 2006  
Bothell, Washington USA