



*Declaration of Conformity*  
According to EN45014



**Manufacturer's Name & Address:**

SonoSite, Inc.  
21919 - 30<sup>th</sup> 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
TITAN® high-resolution mobile ultrasound system	P03073, P03842, P04107, P04240, P04541, P04542, P04543, P04544, P04545, P04546, P06501, P08830, V04240, V04241, V04242, V04243, V04247, V04248, V04541, V04542, V04543, V04544, V04545, V04546, V08830	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, 2<sup>nd</sup> Edition including Amendment 1 and 2
- EN60601-1-1: 1993

**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
- SonoCalc® IMT
- SonoSite C11/8-5 Transducer
- SonoSite C15/4-2 Transducer
- SonoSite C60/5-2 Transducer
- SonoSite HST/10-5 Transducer
- SonoSite ICT/8-5 Transducer
- SonoSite L25/10-5 Transducer
- SonoSite L38/10-5 Transducer
- SonoSite L52/10-5 Transducer

- SiteLink Image Management System
- SiteLink Image Management System with DICOM
- Triple Transducer Connect Module

**OEM Products:**

- Aquasonic 100 Acoustic Gel
- Compact Flash 64MB or 256MB
- Toroid Corp. isolation transformer
- Mitsubishi, VCR, NTSC, MD-3000U
- Mitsubishi, VCR, PAL, MD-3000E
- National Display, 15" Flat Panel Display
- Panasonic DVD Recorder, LQ-MD800
- Sony DVD Recorder, DVO-1000MD
- Sony GV-D900 NTSC digital video recorder
- Sony GV-D800 NTSC digital video recorder
- Sony GV-D800E PAL digital video recorder
- Sony PVM14M2-MDU video monitor
- Sony SVO9500MD NTSC videocassette recorder
- Sony SVO9500MD PAL videocassette recorder
- Sony UP-21MD color thermal video printer
- Sony UP897MD monochrome thermal video printer

**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

November 11, 2008  
Bothell, Washington USA