



Declaration of Conformity
According to EN45014



Manufacturer's Name:

SonoSite, Inc.

European Compliance Representative's Name:

SonoSite, Inc.

Manufacturer's Address:

21919 - 30th 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:

Table with 3 columns: Item/Trade Name, Part Number(s), and Manufacturer. It lists various SonoSite ultrasound systems and their corresponding part numbers and manufacturer information.

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: 1993

EMI / EMC:

- EN60601-1-2:2001

Supplementary Information:

Included are the following Accessories and OEM Products:

Accessories:

- AC Power Supply
Basic Stand
Battery Pack
Biopsy/Needle Guides
CRT Stand
ECG Cable
Grab And Go Carrying Case
PC Direct Serial Cable
ScanPack® Quick Access Carrier
SiteCharge® Dual Battery Charger
SiteLink Image Management System
SiteLink with DICOM 1.0
SiteStand® Mobile Docking Station

- SonoCalc™ IMT
SonoSite C11/7-4 Transducer
SonoSite C15/4-2 Transducer
SonoSite C60/5-2 Transducer
SonoSite C8/8-5 Transducer
SonoSite HST/10-5 Transducer
SonoSite ICT/7-4 Transducer
SonoSite L38/10-5 Transducer
SonoSite L25/10-5 Transducer
SonoSite L52/10-5 Transducer
USB Serial Cable

OEM Products:

- External Flat Panel Display
Aquasonic 100 Acoustic Gel

- Casio EV-660 or EV-670 handheld monitor
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 video cassette recorder
Sony SVO9500MDP PAL video cassette recorder
Sony UP-21MD color thermal video printer
Sony UP2900MD 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)

Handwritten signature of Daina L. Graham

July 31, 2006
Bothell, Washington USA

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