



Declaration of Conformity
According to EN45014

**Manufacturer's Name:**

SonoSite, Inc.

European Compliance Representative's Name:

SonoSite, Ltd.

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(s):**

Item	Part Number(s)	Manufacturer
AC Power Supply	P00538	Ault, Inc.
Basic Stand	P01708	GCX Corporation
Battery Pack	P00049	Centurion International or MicroPower Electronics
CRT Stand	P01881	GCX Corporation
ECG Cable	P01592, P03246	National Cable Molding
Grab And Go Carrying Case	P02724	Techstyles
PC Direct Serial Cable	P02046	National Cable Molding
ScanPack® Quick Access Carrier	P01313	Techstyles
SiteCharge® Dual Battery Charger	P00552	SelfCHARGE Inc.
SonoCalc™ IMT Measurement Software	P05337, P05349, P05960	SonoSite, Inc.
SiteLink Image Management System	P01370	SonoSite, Inc.
SiteLink with DICOM 1.0	P04049	SonoSite, Inc.
SiteStand® Mobile Docking Station	P00375, P01606, P02517	MODO, Inc., Viasystems Group, Inc. or Integrex, Inc.

Complies with:

European Community Council Directive (Medical Device Directive) 93/42/EEC, VII, and are Class I medical device accessories in accordance with Annex IX, Rule 12. In addition, that said products comply with the applicable requirements of:

Safety (when tested as part of the ultrasound system):

- EN60601-1: 1990, Second Edition including Amendment 1 and 2
- EN60601-1-1: 1993

EMI / EMC (when tested as part of the ultrasound system):

- EN60601-1-2:2001

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)
- NO.169:2004, Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-vitro Diagnostic Reagents (2004)

July 31, 2006
Bothell, Washington USADaina L. Graham
Vice-President, Regulatory Affairs and Quality Assurance