



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):

Table with 4 columns: Item, Part Number(s), GMDN Code, Manufacturer. Lists various transducer models and their manufacturing details.

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

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

April 12, 2007
Bothell, Washington USA

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