





Declaration of Conformity
According to ISO/IEC 17050



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 No., GMDN Code, Manufacturer. Lists various transducer models and their corresponding part numbers and manufacturer 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: 2001
EN60601-2-37: 2001 + A1 (2004)

EMI / EMC:

- EN60601-1-2:2007

Quality Management and Quality Assurance:

- ISO 9001:2008, Quality management systems -- Requirements International Organization for Standardization
ISO 13485:2003, Medical devices -- Quality management systems -- Requirements for regulatory purposes

Mary K. Moore (handwritten signature)

August 16, 2010
Bothell, Washington USA

Mary K. Moore
Vice-President of Regulatory Affairs