



Declaration of Conformity
According to ISO/IEC 17050

**Manufacturer's Name & Address:**

SonoSite, Inc.
21919 - 30th Drive SE
Bothell, Washington 98021-3904 USA

European Authorized 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
Transducer, C11x/8-5	P07678, V07678	40767	SonoSite, Inc.
Transducer, C60x/5-2	P07680, V07680	40767	SonoSite, Inc.
Transducer, D2x/2	P05165	40767	SonoSite, Inc.
Transducer, P10x/8-4 MHz	P07696, V07696	40767	SonoSite, Inc.
Transducer, HFL38x/13-6	P07682, V07682	40767	SonoSite, Inc.
Transducer, HFL50x/15-6 transducer	P07693	40767	SonoSite, Inc.
Transducer, ICTx/8-5	P07690, V07690	40771, 40772	SonoSite, Inc.
Transducer, L25x/13-6	P07691, V07691	40767	SonoSite, Inc.
Transducer, L38x/10-5	P07694, V07694	40767	SonoSite, Inc.
Transducer L38xi/10-5	P12742	40767	SonoSite, Inc.
Transducer, L52x/10-5	V00031	40767	SonoSite, Inc.
Transducer, P21x/5-1, Phased Array	P07698, V07698	40767	SonoSite, Inc.
Transducer, SLAx/13-6 MHz	P07699	40770	SonoSite, Inc.
Transducer, TEEEx/8-3 MHz	P05183	37891	GE Vingmed Ultrasound A/S

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:

- | | |
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| <ul style="list-style-type: none"> • EN60601-1: 1990, 2nd Edition including Amendment 1 and 2 • EN60601-1-1: 2001 | <ul style="list-style-type: none"> • EN60601-2-37: 2001 + A1 (2004) |
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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

August 16, 2010
Bothell, Washington USA

Mary K. Moore
Vice-President, Regulatory Affairs