

STATE OF WASHINGTON        )  
                                          )  
COUNTY OF SNOHOMISH    )        ss.

I certify that the attached certificate is a true and correct copy of a document in the possession of SonoSite, Inc. as of this date.

Dated this 10 day of June, 2009.



Jessica R Schram

Jessica R Schram

Printed Name

Notary Public in and for the State of Washington

My appointment expires 4-19-13



*Declaration of Conformity*  
According to EN45014

**Manufacturer's Name:**

SonoSite, Inc.

**European Compliance Representative's Name:**

SonoSite, Ltd.

**Manufacturer's Address:**21919 - 30<sup>th</sup> 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)	GMDN Code	Manufacturer
Transducer, C8e/8-5	P08010, V08010	40767	TETRAD, Inc., W.L. Gore & Associates, Inc.
Transducer, C11e/8-5	P07161, V07161	40767	SonoSite, Inc.
Transducer, C60e/5-2	P05483, P05675, P07633, V05483, V07633	40767	SonoSite, Inc.
Transducer, D2/2	P05165	40767	SonoSite, Inc.
Transducer, HFL38/13-6	P05697, P05674, P07632, V05697, V07632	40767	SonoSite, Inc.
Transducer, ICT/8-5	P04538, P05676, V04538	40771, 40772	SonoSite, Inc.
Transducer, LAP/12-5	P05507	40770	TETRAD, Inc., W.L. Gore & Associates, Inc.
Transducer, L25e/13-6	P06519, P07634	40767	SonoSite, Inc.
Transducer, L38e/10-5	P05482, P05673, V05482	40767	SonoSite, Inc.
Transducer, L52e/10-5	V00030	40767	TETRAD, Inc., W.L. Gore & Associates, Inc.
Transducer, L52x/10-5	V00033	40767	SonoSite, Inc.
Transducer, P10/8-4, Phased Array	P05182, V05182	40767	SonoSite, Inc.
Transducer, P17/5-1, Phased Array	P05661, P05672, P06073, V05661, V06073	40767	SonoSite, Inc.
Transducer, P21e/5-1, Phased Array	P12814	40767	SonoSite, Inc.
Transducer, SLA/13-6	P05174	40770	SonoSite, Inc.
Transducer, SLT/10-5	P05180	40770	TETRAD, Inc., W.L. Gore & Associates, Inc.
Transducer, TEE/8-3	P05183, P05677	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:**

- EN60601-1: 1990, 2<sup>nd</sup> 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 9001:2000 Quality management systems -- Requirements International Organization for Standardization (2000)
- ISO 13485:2003, Medical devices -- Quality management systems -- Requirements for regulatory purposes (2003)

June 8, 2009  
Bothell, Washington USA

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