



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)	GMDN Code	Manufacturer
Transducer, C8/8-5	P03741	40762	Manufactured for SonoSite by W.L. Gore & Associates, Inc.
Transducer, C11/7-4 Neonatal	P01652, P01960, P02268, & P02645	40762	Manufactured by SonoSite, Inc.
Transducer, C15/4-2 MCX	P00798, P01346, P01677, P02099, P02461 P02594 & P03368	40762	Manufactured by SonoSite, Inc. or Manufactured for SonoSite by Parallel Design
Transducer, C60/5-2	P00005, P01150, P01385, P01955, P01958, P02098, P02115, P02133 & P03367	40762	Manufactured by SonoSite, Inc. or Manufactured for SonoSite by Philips Ultrasound
Transducer, HST/10-5	P02954, P03237 & P03542	40762	Manufactured for SonoSite by Philips Ultrasound
Transducer, ICT/7-4 Intracavitary	P00006, P01151, P01343, P01368, P01382, P01956, P02096, P02097, & P02450	40762	Manufactured by SonoSite, Inc. or Manufactured for SonoSite by Philips Ultrasound
Transducer, L38/10-5	P01088, P01910, P01919, P02095, P02421, P02475, & P03366	40762	Manufactured by SonoSite, Inc.
Transducer, L25/10-5	P04034	40762	Manufactured by SonoSite, Inc.
Transducer, L52/10-5	V00018, V00028, V00029	40762	Manufactured for SonoSite by W.L. Gore & Associates, Inc.

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 | <ul style="list-style-type: none"> • EN60601-1-1: 1993 |
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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)
- NO.169:2004, Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-vitro Diagnostic Reagents (2004)

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

April 12, 2007
Bothell, Washington USA