

World leader and specialist in hand-carried ultrasound.

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 6th day of August, 2010.



Jessica R Schram

Jessica R Schram

Printed Name
Notary Public in and for the State of Washington
My appointment expires 4-19-2013



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
SonoSite NanoMaxx™ Series ultrasound system	P11111, V11111	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.

Complies with:

European Community Council Directive (Medical Device Directive) 93/42/EEC as amended by 2007/47/EC, 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:

- | | |
|--|--|
| <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

Supplementary Information:

Included are the following Accessories and OEM Products:

Accessories

Low Noise Power Supply
Battery Pack, Panasonic cells
Battery Pack, Sanyo cells
Biopsy/Needle Guides
NanoMaxx™ Dock
PowerPack
PowerPark
V-Universal Stand

SonoCalc® IMT
SonoSite® WorkFlow Solutions
Wireless Kit
C11n/8-5 Transducer
C60n/5-2 Transducer
ICTn/8-5 Transducer
L25n/13-6 Transducer
L38n/10-5 Transducer
L52n/10-5 Transducer

P21n/5-1 Transducer

OEM Products

Aquasonic 100 Acoustic Gel
CIVCO, Transducer covers
Sony, Black and White Video Printer, UP897MD
USB Barcode Scanner
USB Black and White Printer
USB Printer

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 6, 2010
Bothell, Washington USA

Mary K. Moore
Vice President of Regulatory Affairs