





**Declaration of Conformity**  
According to EN45014



**Manufacturer's Name & Address:**

SonoSite, Inc.  
21919 - 30<sup>th</sup> Drive SE  
Bothell, Washington 98021-3904 USA

**European Authorized Representative's Name & Address:**

Medis (A division of SonoSite, Inc).  
Medizinische Messtechnik GmbH  
Werner-von-Siemens-Str. 8, 98693 Ilmenau Germany

**Declares that the CE-marked product(s):**

Item	Part Number(s)	GMDN Code	Manufacturer
BioZ® Rx Hemodynamic Monitoring System	7101-SYS	41036, 12636	Manufactured by SonoSite, Inc.
Patient Interface Module	5521	12636	Manufactured by SonoSite, Inc.
Slim Point-of-Care Terminal W/15" LCD, Custom	7100	12636	Manufactured by SonoSite, Inc.
BioZ AdvaSense Sensors	4550, 1550,	41036	Manufactured for SonoSite, Inc. by AdvaSense
BioZ AdvaSense Cables	4540, 4545, 5551, 5562	41036	Manufactured for SonoSite, Inc. by AdvaSense

**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:**

- IEC0601-1: 1990, 2<sup>nd</sup> Edition including Amendment 1 and 2
- IEC 60601-2-25: 1999 Medical electrical equipment – Part 2: Particular requirements for the safety of electrocardiographs
- EC0601-2-27: 1994 Medical electrical equipment – Part 2: Particular requirements for the safety of electrocardiographic

monitoring equipment.

**EMI / EMC:**

- IEC0601-1-2:2007

**Supplementary Information:**

Included are the following Accessories and OEM Products:

**Accessories:**

BioZ Rx Cart

**OEM Products:**

BioZ Rx Optional Printer

ECG Accessory Kit

**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*

December 04, 2009  
Bothell, Washington USA

Mary K. Moore  
Vice-President, Regulatory Affairs

