

STATE OF WASHINGTON)
) ss.
COUNTY OF SNOHOMISH)

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 28th day of December, 2009.



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 EN45014

**Manufacturer's Name & Address:**

SonoSite, Inc.
21919 - 30th 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 Cart	7530	37341	Manufactured by GCX

Complies with:

European Community Council Directive (Medical Device Directive) 93/42/EEC as amended by 2007/47/EC, Annex II, and are Class 1 device accessories in accordance with Annex IX. EC Certificate XXXXX 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:

- IEC 60601-1: 1990, 2nd Edition including Amendment 1 and 2

EMI / EMC:

- IEC60601-1-2:2007

Supplementary Information:

Included are the following Accessories and OEM Products:

System:

BioxZ Rx System
Patient Interface Module
Slim Point-of-Care Terminal

W/15" LCD, Custom
BioZ AdvaSense Sensors
BioZ AdvaSense Cables

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