

# Manufacturer's Declaration of Conformity

## Full Quality Assurance Procedure

According To Australian Therapeutic Goods (Medical Devices) Regulations 2002



This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the devices stated in following Schedule.

### Manufacturer's Name & Address:

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

### Australasia Sponsor's Name & Address:

SonoSite Australasia, Ltd.  
Australasia Headquarters  
Suite 205, 14 Rodborough Road, Frenchs Forest NSW 2086 Australia

### Declares that the product(s):

Item	Part Number(s)	GMDN Code	Manufacturer
TITAN® high-resolution mobile ultrasound system	P03073, P03842, P04107, P04240, P04541, P04542, P04543, P04544, P04545, P04546, P06501, V04240, V04241, V04243, V04247	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.

### Scope and Compliance:

Each medical device part number listed above 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 CE 02429 has been issued by the British Standards Institution (BSI) for compliance with Annex II, section 3.2 of the European Council Directive 93/42/EEC. In addition, each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied. In addition, said devices comply with the applicable requirements of:

#### Safety:

- EN60601-1: 1990, 2<sup>nd</sup> Edition including Amendment 1 and 2
- EN60601-1-1: 1993

#### EMI / EMC:

- EN60601-1-2:2001

### Supplementary Information:

Included are the following Accessories and OEM Products:

#### Accessories:

AC Power Supply  
Battery Pack  
ECG Cable  
External 12.1" Flat Panel Display  
Mini Dock  
Mobile Docking System, Mobile Docking System Enhanced (MDSe), Mobile Docking System - Lite  
SonoCalc® IMT  
SonoSite C11/8-5 Transducer  
SonoSite C15/4-2 Transducer  
SonoSite C60/5-2 Transducer  
SonoSite HST/10-5 Transducer  
SonoSite ICT/8-5 Transducer  
SonoSite L25/10-5 Transducer  
SonoSite L38/10-5 Transducer  
SonoSite L52/10-5 Transducer  
SiteLink Image Management System

SiteLink Image Management System with DICOM  
Triple Transducer Connect Module

#### OEM Products:

Aquasonic 100 Acoustic Gel  
Compact Flash 64MB or 256MB  
Toroid Corp. isolation transformer  
Mitsubishi, VCR, NTSC, MD-3000U  
Mitsubishi, VCR, PAL, MD-3000E  
National Display, 15" Flat Panel Display  
Panasonic DVD RECORDER, LQ-MD800  
Sony DVD Recorder, DVO-1000MD  
Sony GV-D900 NTSC digital video recorder  
Sony GV-D800 NTSC digital video recorder  
Sony GV-D800E PAL digital video recorder  
Sony PVM14M2-MDU video monitor  
Sony SVO9500MD NTSC video cassette recorder  
Sony SVO9500MD PAL video cassette recorder  
Sony UP-21MD color thermal video printer  
Sony UP897MD monochrome thermal video printer

### 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)

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

July 2, 2007  
Bothell, Washington USA