

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 - 30th 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, P08830, V04240, V04241, V04243, V04247, V08830	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, 2nd 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 (MDS_e), 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 SVO9500MDP 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

November 11, 2008
Bothell, Washington USA