

# 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:**

SonoSite, Inc.

**Australasia Sponsor's Name:**

SonoSite Australasia, Ltd.

**Manufacturer's Address:**

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

**Australasia Sponsor's Address:**

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

**Declares that the product(s):**

Item/Trade Name	Part Number(s)	GMDN Code	Manufacturer
iLook15™ Personal Imaging Tool	P02245, V02245	40761, 40762, 40763, 40764	Manufactured by SonoSite, Inc.
iLook25™ Personal Imaging Tool	P02976, V02976	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
- Auxiliary Power Cable
- Battery Pack
- Docking Station
- SiteLink Image Management System
- SiteLink with DICOM 1.0
- Stand
- USB Serial Cable

**OEM Products:**

- Sony UP897MD monochrome thermal video printer
- Security Cable

**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)

July 31, 2006  
Bothell, Washington USA

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