CSA INTERNATIONAL

Certificate of Compliance

Certificate: 2164381 **Master Contract:** 201161

Project: 2303550 **Date Issued:** August 17, 2010

Issued to: **SonoSite, Inc.**

21919 30th Dr SE
Bothell, WA 98021-3904
USA
Attention: Jean Bishop

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US or with adjacent indicator 'US' for US only or without either indicator for Canada only.

C US

Joseph Poon

Issued by: Joseph Poon, AScT

PRODUCTS

CLASS 8750 01 - MEDICAL ELECTRICAL EQUIPMENT
CLASS 8750 81 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS - Certified to US Standards

Diagnostic Ultrasound System, Nano Series Ultrasound System, mobile, cord connected, consisting of a dedicated external power supply, 'Elpac Electronics', model 4083F, a control unit, model NanoMaxx or NanoPICC with ultrasound transducers, a dock/port replicator, model Nano Dock, V-Universal stand, PowerPark Stand Module, and accessories, rated 100-240 V, 50-60 Hz, 2.0-1.0 A, or internally powered, battery operated.

Notes:

1. Type of protection against electric shock: Class I or Internally powered/battery operated

2. Degree of protection against electric shock: Transducers - Type BF; ECG - Type CF

3. Degree of protection against ingress of water: System IPX0, Ultrasound probe to IPX7

4. Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

5. Mode of operation: Continuous

6. Environmental Conditions: Normal: 10-40°C, 15-95% rH, 700-1060hPa

APPLICABLE REQUIREMENTS

CAN/CSA C22.2 601.1-M90 - Medical Electrical Equipment part 1: General requirements for Safety adopted IEC 601-1 2ed (90)

CAN/CSA C22.2 601.1S1-94 - Supplement No 1-94 to CAN/CSA C22.2 601.1-M90

CAN/CSA C22.2 601.1B-98 - Amendment 2 to CAN/CSA C22.2 601.1-M90

CAN/CSA C22.2 60601-2-37-03 - Medical Electrical Equipment part 2-37: Particular requirements for the safety of Ultrasonic Medical Diagnostic and Monitoring Equipment adopted IEC 60601-2-37 (01)

CAN/CSA C22.2 60601-2-37A-05 - Amendment 1:2005 to CAN/CSA C22.2 60601-2-37-03 Medical Electrical Equipment part 2-37: Particular requirements for the safety of Ultrasonic Medical Diagnostic and Monitoring Equipment adopted am 1 to IEC 60601-2-37 (01), am1 (04)

CAN/CSA C22.2 60601-1-1-02 - Medical Electrical Equipment part 1-1: General requirements for Safety - Collateral Standard Safety Requirements for Medical Electrical Systems adopted IEC 60601-1-1 (2000)

UL 60601-1 (1st edition) - Medical Electrical Equipment part 1: General requirements for Safety

Reference Standards

IEC Publication 601-1 (1988) + A1 (1991) + A2 (1995) - Safety of Medical Electrical Equipment, Part I: General Requirements for Safety

IEC 60601-2-37 (2001) + A1 (2004) + A2 (2005) - Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment

IEC 60601-1-1(2000) -Collateral Standard: Safety Requirements for Medical Electrical Systems

Subject to the followingqualifications:

(1) The equipment has not been investigated for the protection against hazards of explosions in medically used rooms.

(2) The main supply cord set provided with the equipment must be an approved type acceptable to the authorities in the country where the equipment is sold.

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(3) Evaluated to IEC/CSA 601□1 Amendment 2 excluding requirements for Electromagnetic compatibility (Clause 36), Biocompatibility (Clause 48) and Programmable Electronic Systems (IEC 60601□1□4 referenced in sub□clause 52.1).

(4) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.