



Certificate of Compliance

Certificate: 1624290 (LR 115987)

Master Contract: 201161

Project: 2502786

Date Issued: March 15, 2012

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.



Joseph Poon

Issued by: Joseph Poon, ASCT

PRODUCTS

CLASS 8750 01 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS

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

Diagnostic Ultrasound System, Models MicroMaxx Ultrasound System, MiniDock, Mobile Docking System and accessories, with external power supply rated 100-240 V, 50-60 Hz, 2.0 – 1.0 A; or Battery Operated.

Notes

1. Type of protection against electric shock: Class I equipment (when powered from power supply or part of the Mobile Docking System); and Internally powered equipment (MicroMaxx Ultrasound System w/o power supply).
2. Degree of protection against electric shock: Type BF (Ultrasound Transducers) and Type CF (ECG Leads).
3. Degree of protection against ingress of water: IPX7 (transducers)
4. Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.



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5. Mode of operation: Continuous

6. Environmental Conditions: Extended: 10-40°C, 15-95% RH (non-condensing), 700 to 1060 hPa

APPLICABLE REQUIREMENTS

CAN/CSA C22.2 601.1-M90 - Medical Electrical Equipment part 1: General requirements for Safety

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

CAN/CSA C22.2 60601-2-37A-05 - Amendment 1:2005 to CAN/CSA C22.2 60601-2-37-03

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

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) - 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 following qualifications:

(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.

(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).



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