Certificate of Compliance

Certificate: 1934871 (LR 115987) **Master Contract:** 201161

Project: 2594408 **Date Issued:** February 14, 2013

Issued to: **FUJIFILM SonoSite, Inc.**

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USA
Attention: John Prieve

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 M-Turbo and Edge Ultrasound Systems, rated 100-240 V, 50-60 Hz, 2.0- 1.0 A or Battery Operated; Type BF Patient Applied Part (Ultrasound Transducers) and Type CF defib-proof (ECG Leads).

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 (Ultrasound System w/o power supply)

2. Degree of protection against electric shock: Type BF transducers / Type CF ECG leads

3. Degree of protection against ingress of water: IPX7 for ultrasound probes only

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.

5. Mode of operation: Continuous (35ºC or below) and Non-continuous (between 35 - 40ºC)

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

APPLICABLE REQUIREMENTS

CAN/CSA C22.2 No 601.1-M90 - Safety of Medical Electrical Equipment, Part I, General Requirements for Safety

CSA 601.1 Supplement 1:1994 - Supplement No 1-94 to CAN/CSA C22.2 601.1-M90

CSA 601.1 Amendment 2:1998 - Amendment 2 to CAN/CSA C22.2 601.1-M90

CAN/CSA C22.2 No. 60601-1-1-02 - Collateral Standard: Safety Requirements for Medical Electrical Systems

CAN/CSA C22.2 No. 60601-2-37-03 - Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment

CAN/CSA C22.2 No. 60601-2-37A-03 - Amendment 1:2005 Medical Electrical Equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

UL Std No 60601-1 (1st Edition) - Safety of Medical Electrical Equipment, Part I: General Requirements for Safety

REFERENCE STANDARDS

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

IEC 60601-2-37:2001 + am1 (2004) + am2 (2005) - Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment

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).

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