Certificate of Compliance

Certificate: 1966761 **Master Contract:** 201161

Project: 2615669 **Date Issued:** April 24, 2013

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

21919 30th Dr SE
Bothell, WA 98021-3904
USA
Attention: Linda Foster

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.

Mehrdad Sadeghieh

Issued by: Mehrdad Sadeghieh, P. Eng.

PRODUCTS

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

Diagnostic Ultrasound System, Models S Series, rated 100-240 V, 50-60 Hz, 2.0- 1.0 A (Ultrasound System), or Battery Operated; Type BF Patient Applied Part (Ultrasound Transducers).

Notes:

1. Type of protection against electric shock: Class I equipment (when powered from power supply or part of the S Series Stand System); and Internally powered equipment (S Series Ultrasound System w/o power supply).

2. Degree of protection against electric shock: Type BF (transducers)

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.

5. Mode of operation: Continuous

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

7. May include S Series Stand, V-Universal Stand, PowerPark Stand, and accessories described in this report.

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 CSA 601.1 Amendment 2:1998

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 + A1:2005 - 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 1: General Requirements for Safety

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

REFERENCE STANDARDS

IEC Standard 601.1:1998 + A1:1991 + A2:1995 - Medical Electrical Equipment Part 1: General Requirements for Medical Electrical Systems

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

IEC Standard 60601-2-37 +A1:2004 + A2:2005 - Medical Electrical Equipment Part 2: 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 (Clause 52.1).

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