Certificate of Compliance

Certificate: 2640923 **Master Contract:** 201161

Project: 2640923 **Date Issued:** September 6, 2013

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

21919 30th Dr SE
Bothell, WA 98021-3904
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.

Juan-Carlos Olivera

Issued by: Juan-Carlos Olivera, MSc.

PRODUCTS

CLASS 8780 01 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS 8780 81 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS - Certified to US Standards

Diagnostic Ultrasound System, Model X-Porte, rated: 100-240 V, 50-60 Hz, 3.4-1.4A, AC/DC Power Supply Source or 100-240 V, 50-60 Hz, 8.0-3.0A, Stand Power Management Unit Source 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 (when powered from external AC/DC power supply)

Class I (when powered from stand mounted AC/DC power supply / charger)

Internally powered (when powered from stand mounted battery packs)

2. System includes optional X-Porte Dock and accessories.

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

4. Degree of protection against ingress of water: IPX7 for ultrasound transducers/probes only, IPX8 footswitch.

5. 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.

6. Mode of operation: Continuous.

7. Environmental Conditions: Normal: 10-40°C, 15-95% (non-condensing) rH, 700-1060hPa

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1-08 - Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance (Adopted IEC 60601-1:2005 + CORR.1)

CAN/CSA-C22.2 No. 60601-1:08 TC 2:2011 (Corrigendum 2) - Technical Corrigendum 2:2011 to CAN/CSA-C22.2 No. 60601-1:08 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 - CORR.2)

CAN/CSA C22.2 60601-1-6-08 - Medical Electrical Equipment part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability adopted IEC 60601-1-6 (06) Ed. 2

CAN/CSA C22.2 60601-2-37-08 - Medical Electrical Equipment part 2-37: Particular requirements for the basic safety and performance of ultrasonic medical diagnostic and monitoring equipment, adopted IEC 60601-2-37(07) Ed 2.0

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD) - Medical electrical equipment, Part 1: General requirements for basic safety and essential performance + C1:2009 + A2:2010

Reference Standards:

IEC 60601-1:2005 - Medical electrical equipment, Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6:2006 - Medical electrical equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 60601-2-37:2007 - Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

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Subject to the following qualifications:

1. 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.

2. Units provided with other than North American Certified power supply cord sets are certified as a component.

3. The user replaceable mains (line) fuse must be an approved type acceptable to the authorities where the equipment is sold.

4. Evaluated to CAN/CSA-C22.2 No. 60601-1-08 and ANSI/AAMI ES60601-1:2005 excluding requirements for Electromagnetic Compatibility (Clause 17), Usability (Clause 12.2), Biocompatibility (Clause 11.7)

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

6. Interconnection of this medical device with other medical devices, medical used systems or non medical devices shall be evaluated to the requirements of Clause 16 in the end use application.