Certificate of Compliance

Certificate: 2641379 **Master Contract:** 201161

Project: 2641379 **Date Issued:** September 10, 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

Ultrasound Transducers, Models C60xp/5-2, HFL50xp/15-6, ICTxp/9-5, L25xp/13-6, L38xp/10-5, and P21xp/5-1 powered by certified Fujifilm SonoSite Ultrasound System through proprietary connector, handheld, Type BF patient applied part, component.

Notes:

1. Type of protection against electric shock: N/A (component approval only. Depending on host equipment.)

2. Degree of protection against electric shock: Type BF

3. Degree of protection against ingress of water: 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 (can be non-continuous depending on host equipment)

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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)

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

ANSI/AAMI ES60601-1:2005 / C1:2009 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Corrigendum C1

ANSI/AAMI ES60601-1:2005 / A2:2010 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment A2

Reference Standards:

IEC Publication 60601-1 (2005) - Medical Electrical Equipment, Part I, General Requirements for basic safety and essential performance

Subject to the following qualifications:

(1) These transducers have been evaluated as components, intended to be used with manufacturer's medical equipment. The combination will be evaluated at the end product.

(2) Evaluated to the requirements of the referenced standards, excluding the requirements related to RISK MANAGEMENT, which will be addressed in the end product, as per manufacturer's request.

(3) Evaluated to the requirements of the referenced part 1 standards, excluding requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7). The requirements of the particular standard (-2-37) will be addressed in the end product.

(4) Power source supplying transducers must be less than 15W to allow the HB enclosure material

(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.