CSA INTERNATIONAL

Certificate of Compliance

Certificate: 1412417 (LR 115987) **Master Contract:** 201161

Project: 1940321 **Date Issued:** 2007/08/15

Issued to: **SonoSite, Inc.**

21919 30th Dr SE
Bothell, WA 98021-3904
USA
Attention: Mr. Matt Hedlund

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US'

C US

Issued by: Cindy Johnson, AScT.

Authorized by: Ken Rutledge, Product Group Manager

PRODUCTS

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

Titan Ultrasound System, MiniDock, Mobile Docking System, and accessories; rated 100-240 V ac, 50-60 Hz, 1.2- 0.6 A (with P.S. 3292 or 3481) or 2.0-1.0 A (with P.S. 3941F) (Ultrasound System/MiniDock), and 4-2 A (Mobile Docking System); or Battery Operated; Type BF Patient Applied Part.

Note: The above product is Equipment Class I (when powered from a power supply or part of the Mobile Docking System), and Class II (for the Titan Ultrasound System without power supply).

The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL, i.e. National Recognized Testing Laboratory, is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

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APPLICABLE REQUIREMENTS

CAN/CSA-C22.2 No. 601.1 - Medical Electrical Equipment Part 1: General Requirements for Safety

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

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

UL Std. 60601-1 (1st Edition) - Medical Electrical Equipment Part I: General Requirements for Safety

IEC 60601-1-1 (2000) - Medical Electrical Equipment Part 1: General Requirements for Safety - 1. Collateral Standard: Safety Requirements for Medical Electrical Systems.

IEC 60601-2-37 (2004-10) - Ed. 1.1 Consolidated Edition. Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

IEC 60601-2-37-am1 (2004-08) Amendment 1 - Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

Subject to the following qualifications:

- The equipment has not been investigated for the protection against hazards of explosions in medically used rooms.
- 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.
- 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).

CSA INTERNATIONAL

Supplement to Certificate of Compliance

Certificate: 1412417 **Master Contract:** 201161

The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.

Product Certification History

Project	Date	Description
1940321	2007/08/15	Update report 1412417 to include alternative power supply.
1896105	2007/04/05	Update report to include Sony DVO peripheral.
1880237	2007/02/07	Update report to include alternative Display Monitor.
1832338	2006/09/11	Correction of 60601-1-1 standard edition.
1771007	2006/05/30	Update report to update standards.
1476059	2005/09/10	Update to Report 1412417 to Include Triple Transducer Option (Ref.: Titan System) (C/US)
1603178	2004/11/05	Update to include the MDS Lite Cart, alternate transducers, and optional DVD and VCR.
1576730	2004/07/14	Update to remove model designations.
1558969	2004/05/21	Update to Add Alternate Power Supply.
1494389	2004/02/27	Update to Report 1412417 to Include Alternate Transducer and 12" LCD (C/US)

History

1412417	2003/05/09	Original Certification.

Ref. Certif. No.

CA/8934/CSA

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product Produit	Diagnostic Ultrasound System and Accessories
Name and address of the applicant Nom et adresse du demandeur	SonoSite, Inc. 21919 - 30th Drive S.E., Bothell, WA 98024-3904 USA
Name and address of the manufacturer Nom et adresse du fabricant	Same as applicant
Name and address of the factory Nom et adresse de l'usine Note: *When more than one factory, please report on page 2* Note: *Lorsque il y plus d'une usine, veuillez utiliser la 2ème page*	Same as applicant ☐ Additional Information on page 2
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	100-240 V ac, 50-60 Hz, 1.2-0.6 A (with P.S. 3292 or 3481) or 2.0-1.0 Amp (with P.S. 3941F) (Ultrasound System/MiniDock), and 4-2 A (Mobile Docking System); or battery operated, Type BF Patient Applied Part
Trademark (if any) Marque de fabrique (si elle existe)	SonoSite®
Model / Type Ref. Ref. De type	Titan Ultrasound System, MiniDock, Mobile Docking System, and accessories
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2ème page	Tested under the SMT Procedure (Certificate No. SMT-013) ☐ Additional Information on page 2
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1, Edition 2:1988 Amendment No 1 (1991) and Amendment No 2 (1995), excluding requirements for Electromagnetic Compatibility (Clause 36), Biocompatibility (Clause 48) and Programmable Electronic Systems (Clause 52.1); 60601-1-1(2000), 60601-2-37 (2001) + A1:2004 and CA and US National Differences, per CB Bulletin 112a.
As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	201161-1412420 (Project 1940322)

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**

CSA International
178 Rexdale Boulevard
Toronto, ON M9W 1R3

Date: August 16, 2007

Signature: Gianluca Arcari, P.Eng., MBA