Certificate of Compliance

Certificate: 70184307 **Master Contract:** 181257

Project: 70209009 **Date Issued:** 2019-01-07

Issued to: Lantronix, Inc.
7535 Irvine Center Drive
Irvine, California 92618
USA

Attention: Michael Simonsen

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.

Issued by: Robert Chan
Robert Chan

PRODUCTS

CLASS - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS-Certified to US Standards

IoT Device Gateway, Model: SGX 5150 MD (No Serial Port, RS232 1-Port, and RS232 2-Port), Stationary/Fixed, powered by AC/DC Power Adapter, Model: ME10A1272F02, cord-connected through appliance coupler, rated: 100-240 Vac, 50/60 Hz, 0.5A (0.5A-0.2A) and 12Vdc output at 1.0A.

1. Medical device protection against electric shock: Class I with Class II construction.
2. Applied Part protection against electric shock: No applied part.
3. Degree of protection against ingress of water or particulate matter: IP20.
4. Method of Sterilization: None.
5. Medical device not intended to be used in an Oxygen Rich Environment.
6. Medical device not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
7. Mode of operation: Continuous.
8. Environmental Conditions: Normal: 0-45°C, 20-90% 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 No. 60601-1:14	CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)

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
ANSI/AAMI ES60601-1:2005/(R)2012 - AND A1:2012, C1:2009/(R)2012 AND A2:2010/(R)2012 (Consolidated text - edition 3.1)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD).

CONDITIONS OF ACCEPTABILIY:

1. The interconnection of this equipment with other medical devices, medical systems, or other non-medical devices shall be evaluated to the requirements of Clause 16 of IEC60601-1 in the end use application.
2. This equipment shall only be powered by a certified AC/DC Power Adapter (SL Power Electronics P/N: ME10A1272F02) supplied by the manufacturer with the equipment.
3. The mains supply cord set provided with the equipment must be an approved type acceptable to the authorities in the country where the equipment is sold.
4. Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005 excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17) and Biocompatibility (Clause 11.7).

5. SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
6. Safety Risk Management: A risk management process complying with the requirements of standard ISO 14971 was inspected during the evaluation of this medical device and/or additional considerations were taken into account since the subject legacy medical device was evaluated to the previous edition of this standard. During the evaluation of this medical device, the risk management decisions affecting the test requirements have been taken into consideration. Changes/Updates in risk management documents that affect the safety of this medical device during its lifecycle shall be communicated to the CSA Group as a condition for continued certification.

MARKINGS

The manufacturer is required to apply the following markings:

- Products shall be marked with the markings specified by the particular product standard.
- Products certified for Canada shall have all Caution and Warning markings in both English and French.

Additional bilingual markings not covered by the product standard(s) may be required by the Authorities Having Jurisdiction. It is the responsibility of the manufacturer to provide and apply these additional markings, where applicable, in accordance with the requirements of those authorities.

The products listed are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US (indicating that products have been manufactured to the requirements of both Canadian and U.S. Standards) or with adjacent indicator 'US' for US only or without either indicator for Canada only.

On the Equipment Exterior:
Equipment is plainly marked in a permanent manner in a place where the details will be readily visible after installation with the following:

- The CSA applicable mark / / with optional reference to Standard, CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 as per adopted IEC 60601-1:2005 3rd edition
- Manufacturer's identification: Name and/or CSA file number on the same label as the CSA Mark. The name and/or trademark should appear elsewhere on the equipment if only the file number is used on this label.
- Catalogue/Model/Type designation.
- Date of manufacture: Month and year of manufacture or date code. If a serial number is used instead of date of manufacture, a record of serial numbers shall be kept traceable to date of manufacture. (Not related to date of sale).
- Marking on the unit that indicates the manufacturing location if the equipment is manufactured at more than one factory location.
- Complete electrical ratings; in volts (V), hertz (Hz), and amperes (A), Volt-amperes (VA) or Watts (W) with the IEC 60417-5032 alternating current symbol adjacent to the marked AC voltage and dc current symbol IEC 60417-5031 marked adjacent to DC input rating for each model.
- The "CAUTION" symbol ISO 7000-0434A on the nameplate, and/or on each or near each output, prefacing CAUTION labels and adjacent to SIP/SOPs.

- The Caution symbol IEC 60417-5036 or the Warning safety symbol IEC 60878 (ISO 3864-B.3.6) indicating dangerous voltage.
- On the power supply cord or on the equipment there is a tag or label indicating that "GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED 'HOSPITAL ONLY' OR 'HOSPITAL GRADE' " or equivalent wording.
- Protection against ingress protection according to IEC 60529, IPXX rating (designated power supply marked for IP rating, IP22).

Supplement to Certificate of Compliance

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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
70209009	2019-01-07	Update CSA Report 70184307 to remove the Dielectric Strength Factory Test. Also added information in critical components list.
70184307	2018-09-04	C/US Certification for IoT Device Gateway, Model: SGX 5150 MD (No Serial Port, RS232 1-Port, and RS232 2-Port).