Certificate of Compliance

Certificate: 70184307 **Master Contract:** 181257

Project: 80091138 **Date Issued:** 2021-07-23

Issued To: **Lantronix, Inc.**
7535 Irvine Center Drive
Irvine, California, 92618
United States

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: *Natasha Amadasun*
Natasha Amadasun

C US

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.

Conditions of Acceptability:

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/(R)2012 - AND A1:2012, C1:2009/(R)2012 AND A2:2010/(R)2012 (Consolidated text - edition 3.1) 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.

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).

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.

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
80091138	2021-07-23	Update to critical component list within C/US report 70184307 to add generic alternate markings label material indicating INT. Update the technical information for labels in the CCL to indicate label properties; Material type, dimensions, color, impression type, and adhesive type.
000070209009	2019-01-07	Update CSA Report 70184307 to remove the Dielectric Strength Factory Tests
000070184307	2018-09-04	C US Certification for SGX 5150 Wireless IoT Gateway. Quote assumes testing of one model with max number and types of ports to represent all models covered. Assumes optional external pow er supply to be included for evaluation, along with all certification evidence for the power supply (CB and NRTL). Reports to include external power supply as an optional item. Scope covers the requirements of 60601-1 3rd edition including Am1, as well as evaluation of risk management and usability per the s tandard requirements.