Certificate of Compliance

Certificate: 70219456 **Master Contract:** 275029

Project: 70219456 **Date Issued:** 2019-11-27

Issued To: **Excelsys Technologies Ltd.**
27 Eastgate Business Park
Little Island, Cork, CK, 0000
Ireland

Attention: Diarmuid Hogan

Issued by: Wei Shi
Wei Shi

PRODUCTS

CLASS - C531128 - POWER SUPPLIES - Component Type For Use in Medical Equipment/System
CLASS - C531198 - POWER SUPPLIES - Component Type - For Use in Medical Equipment/System-Certified to US Std

Medical Electrical Component of Switching Mode Power Supply, Model: CX10M-uvwxyz-defgh (CoolX CoolPac with CoolMod), CX10M-000000-defgh (CoolX CoolPac without CoolMod); Rated: Input: 100-240Vac, 50-60Hz, 8A – 4.7A, Class I, no applied part, Output: 1000W maximum (see in General Information for details)

Notes:

1. See General Product Information of CSA report #70219456 for definitions of u, v, w, x, y, z, d, e, f, g, h.
2. Medical device protection against electric shock: Class I
3. No applied Part provided
4. Degree of protection against ingress of water or particulate matter: normal
5. Mode of operation: Continuous
6. Environmental Conditions: Normal operating: -25-40°C, 5-95% RH, normal hPa, Altitude up to 5000m max.

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).

Subject to the following qualifications:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Usability (Clause 7.1.1 and 12.2), Biocompatibility (Clause 11.7)

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

(3) 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.

(4) 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.

Conditions of Acceptability:

End product to determine the acceptability of risk in conjunction to the use of Pre-set controls as part of the power supply.

Consideration must be given to the following at end applications:

- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1).
- End product Risk Management Process to consider the need for simultaneous fault condition testing.
- End product Risk Management Process to consider the need for different orientations of installation during testing.
- End product Risk Management Process to determine risk acceptability criteria.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.

- End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply
- End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply
- End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply
- End product to determine the acceptability of risk in conjunction to the leakage current and dielectric strength tests
- End product to determine the acceptability of risk in conjunction to the temperature test in the end use.

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.

See CSA report #70219456 for markings in details.

Marking Method: The above markings are made via silk screening, die stamping, moulding or on CSA certified or UL recognized adhesive nameplate material compatible with the surface used, or other equivalent permanent means that can pass the label rub test as per 7.1.3

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
70219456	2019-11-27	Initial CSA C-US Certification for the Switching Mode Power Supply model CX10M for medical applications according to 60601-1 3rd Edition