Certificate of Compliance

Certificate: 80010163 **Master Contract:** 275029

Project: 80046724 **Date Issued:** 2020-06-16

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

Attention: Diarmuid Hogan

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: *Darya Moshrefi*
Darya Moshrefi

C US

PRODUCTS

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

Medical Electrical Component of Switching Mode Power Supply, Model: CS10c-de-fghjklm, Rated: Input: 100-240Vac, 50-60Hz, 8.5A – 5A, Class I, no applied part, Single Output 24Vac to 48Vac with 1000W maximum (see in General Information for details)

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 use of Pre-set controls as part of the power supply.

- End product to determine the acceptability of risk in conjunction to the derating of the power supply. Refer to general information section for derating details.
- End product to determine the acceptability of risk in conjunction to normal use and single fault conditions in Oxygen rich environment.

End product to determine the acceptability of risk in conjunction to use with flammable agents and flammable anaesthetics.

MARKINGS

[Click **here** and type] 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.

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On the Equipment Exterior:

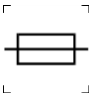
Equipment is plainly marked in a permanent manner in a place where the details will be readily visible after installation with the following:

- 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 "GENERAL WARNING SIGN" symbol ISO 7010-W001 visible in NORMAL USE near MULTIPLE SOCKET-OUTLET, near mechanical protective device intended for single-use, or near relevant outlet when defibrillation-proof protection relies partly on the patient cable.
- The Caution symbol IEC 60417-5036 or the Warning safety symbol IEC 60878 (ISO 3864-B.3.6) indicating dangerous voltage.

The following General Symbols (Table D.1) shall be applied as indicated

Indicate X in column if used	Symbol	Standard Reference	Title	Indicate X in column if used	Symbol	Standard Reference	Title
		IEC 60417-5032	Alternating current			IEC 60417-5010	"ON" / "OFF" (push-push)
		IEC 60417-5032-1	Three-phase alternating current			IEC 60417-5011	"ON" / "OFF" (push button)
		IEC 60417-5032-2	Three-phase alternating current with neutral conductor			IEC 60417-5264	"ON" for part of the EQUIPMENT
		IEC 60417-5031	Direct current			IEC 60417-5265	"OFF" for part of the EQUIPMENT
		IEC 60417-5033	Both direct and alternating current			IEC 60417-5638	Emergency stop
X		IEC 60417-5019	Protective earth (ground)			IEC 60417-5840	TYPE B APPLIED PART
		IEC 60417-5017	Earth (ground)			IEC 60417-5333	TYPE BF APPLIED PART
		IEC 60417-5021	Equipotentiality			IEC 60417-5335	TYPE CF APPLIED PART
		IEC 60417-5172	CLASS II equipment			IEC 60417-5841	Defibrillation-proof TYPE B APPLIED PART
X		ISO 7000-0434A	Caution In case of application as a safety sign, the rules according to			IEC 60417-5334	Defibrillation-proof TYPE BF APPLIED PART

Indicate X in column if used	Symbol	Standard Reference	Title	Indicate X in column if used	Symbol	Standard Reference	Title
			ISO 3864-1 are to be adhered to. See safety sign ISO 7010-W001 (Table D.2, safety sign 2).				
X		ISO 7000-1641	Operating Instructions			IEC 60417-5336	Defibrillation-proof TYPE CF APPLIED PART
		IEC 60417-5007	"ON" (power)			IEC 60417-5036	Dangerous voltage
		IEC 60417-5008	"OFF" (power)			ISO 7000-1051	Do not reuse
		IEC 60417-5016 *	Fuse	**X**		IEC 60417-5041*	Caution , hot surface

The following Safety Signs (Table D.2) shall be applied as indicated

Indicate X in column if used	Safety Sign	Standard Reference	Title	Indicate X in column if used	Safety Sign	Standard Reference	Title
		ISO 7010-W001	General warning sign			ISO 7010-M001	General mandatory action sign
X		ISO 60878/ISO 3864-B.3.6	Caution risk of electric shock or Attention Dangerous Voltage			IEC 60878 Safety 01	Follow operating instructions
		ISO 7010-xxx2	Pushing prohibited			ISO 7010-M002	Refer to instruction manual/ booklet

Indicate X in column if used	Safety Sign	Standard Reference	Title	Indicate X in column if used	Safety Sign	Standard Reference	Title
		ISO 7010-xxx3	Sitting prohibited			Figure 14 of IEC 60825-1*	Warning label - Hazard symbol Radiation of laser apparatus
		ISO 7010-xxx4	Stepping prohibited				

* Note: Not part of the TABLE D.2

On the Equipment Interior:

- The IEC 60417-5019 "Protective earth" symbol adjacent main protective earth terminal;
- Fuse rating, Volts, Amps, type, and breaking capacity adjacent to fuse-holders; or …
- Fuse Designation on Printed Circuit Boards;
- The ISO 3864, No. 5036 electric shock;

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

Certificate: 80010163 **Master Contract:** 275029

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
80046724	2020-06-16	Update and correction of cCSAus Certification 80010163 to change the rating and certification number on the critical component list for TIW wire, Hoi Luen on L6 from UL to VDE
80010163	2020-05-28	Initial CSA Certification for the CS1000 device for medical applications according to 60601-1 3rd Edition