Certificate of Compliance

Certificate: 80177609 **Master Contract:** 158114

Project: 80177609 **Date Issued:** 2023-10-11

Issued To: **Delta Electronics, Inc.**
3, Tungyuan Road,
Chungli Industrial Zone
Taoyuan, Taoyuan City, 32063
Taiwan

Attention: Sam Tien

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: Antonio Joo

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 Standards

Medical Electrical Component*, AC/DC Adapter, Model/Type: MEA-065A12B X1X2X3, MEA-065A15B X1X2X3, MEA-065A19B X1X2X3, MEA-065A24B X1X2X3 (Where X1, X2, X3 can be any alphanumeric character or blank); MEA-065Z12BA X1X2, MEA-065Z15BA X1X2, MEA-065Z19BA X1X2, MEA-065Z24BA X1X2 (Where X1, X2 can be any alphanumeric character or blank), cord-connected: Appliance coupler, Portable, rated: 100-240 Va.c., 50-60 Hz, 1.5-0.75 A and See the electrical output rating below.

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Input Voltage (Va.c.)	Input Frequency (Hz)	Input Current (A)	Output Voltage (Vd.c.)	Max. Output Current (A)	Ambient (ºC)	Max. Output Watt (W)
For model MEA-065A12B X1X2X3, MEA-065Z12BA X1X2						
100-240	50-60	1.5-0.75	12	5	40	60
For model MEA-065A15B X1X2X3, MEA-065Z15BA X1X2						
100-240	50-60	1.5-0.75	15	4.33	40	65
For model MEA-065A19B X1X2X3, MEA-065Z19BA X1X2						
100-240	50-60	1.5-0.75	19	3.42	40	65
For model MEA-065A24B X1X2X3, MEA-065Z24BA X1X2						
100-240	50-60	1.5-0.75	24	2.71	40	65
Additional ambient and load conditions below are tested per applicant's request						
For model MEA-065A12B X1X2X3, MEA-065Z12BA X1X2						
100-240	50-60	1.5-0.75	12	2.5	60	30
For model MEA-065A15B X1X2X3, MEA-065Z15BA X1X2						
100-240	50-60	1.5-0.75	15	2.17	60	33
For model MEA-065A19B X1X2X3, MEA-065Z19BA X1X2						
100-240	50-60	1.5-0.75	19	1.71	60	33
For model MEA-065A24B X1X2X3, MEA-065Z24BA X1X2						
100-240	50-60	1.5-0.75	24	1.36	60	33

1. Medical device protection against electric shock: Class II
2. Applied Part protection against electric shock: No applied part
3. Degree of protection against ingress of water or particulate matter: IP22
4. Method of Sterilization: Heat/Liquid/Gas/Irradiation/Other methods validated and described by the manufacturer/None
5. Suitability for use in an Oxygen Rich Environment: Medical device not intended to be used in an Oxygen Rich Environment
6. Suitability to use Medical device in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: 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: -20-40 °C, 20-90 % R.H., 540-1 060 hPa

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:14 (R2018)	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, third edition + Amendment 1:2012)
Amendment 2:2022 to CSA-C22.2 No. 60601-1:14	Amendment 2:2022 to 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, third edition/Amendment 2:2020)
CAN/CSA-C22.2 No. 60601-1-6:11 (R2016)	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral standard: Usability
Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-6:11 (R2016)	Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-6:11 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition/Amendment 1:2013)
Amendment 2:2021 to CSA-C22.2 No. 60601-1-6:11	Amendment 2:2021 to CAN/CSA-C22.2 No. 60601-1-6:11 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition/Amendment 2:2020)

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005/ (R)2012, AND A1:2012, C1:2009 (R2012) AND A2:2010(R)2012 (CONSOLIDATED TEXT)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD).
ANSI/AAMI ES60601-1:2005/ A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance – Amendment 2 (IEC 60601-1:2005/A2:2020)).

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Subject to the following qualifications:

(1) A Medical Electrical Equipment or Medical Electrical System which is not provided with a North American Certified power supply cord set is certified as a component or a sub-assembly.
(2) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 + Amendment 2 and ANSI/AAMI ES60601-1: 2005/(R)2012, AND A1:2012, C1:2009(R2012) AND A2:2010(R)2012 + Amendment 2 excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7).
(3) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
(4) Interconnection of this medical system 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.
(5) 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.
(6) Scope of AC/DC adaptor evaluation defers the following clauses to be determined as part of the end product investigation:
- Clause 7.9 Accompanying Documents
- Clause 16 ME System
- Risk Management was excluded from this investigation
(7) The subject AC/DC adaptor has been evaluated for 5 000 m altitude application.
(8) The subject AC/DC adaptor has been evaluated for use in a pollution degree 2 environment.
(9) The insulation system classification of the transformers is as followings:
- T1 Switching transformer: Class B

Notes:

Products certified under Class C531128 have been certified under CSA's ISO/IEC 17065 accreditation with the Standards Council of Canada (SCC). www.scc.ca

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
80177609	2023-10-11	Original certification, AC/DC ADAPTER, Model Name: 1. MEA-065A12B X1X2X3, MEA-065Z12BA X1X2; 2. MEA-065A15B X1X2X3, MEA-065Z15BA X1X2; 3. MEA-065A19B X1X2X3, MEA-065Z19BA X1X2; 4. MEA-065A24B X1X2X3, MEA-065Z24BA X1X2 (X1, X2, X3 can be any alphanumeric character or blank)