

Certificate of Compliance

Certificate:	80175805	Master Contract:	158114
Project:	80197620	Date Issued:	01/26/2024
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: Kevin Chang Kevin Chang

PRODUCTS

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

Medical Electrical Component*, AC/DC Adapter

Model/Type: MEA-160A12C X1X2X3, MEA-160A15C X1X2X3, MEA-160A19C X1X2X3, MEA-160A24C X1X2X3 (Where X1, X2, X3 can be any alphanumeric character or blank); MEA-160Z12CA X1X2, MEA-160Z15CA X1X2, MEA-160Z19CA X1X2, MEA-160Z24CA X1X2 (Where X1, X2 can be any alphanumeric character or blank), cord-connected: Appliance coupler, Portable, rated: 100-240 Va.c., 50-60 Hz, 2.2-1.0 A and See the electrical output rating below.



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APPLICABLE REQUIREMENTS

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

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 (Adopted IEC 60601-1-6:2010, third edition

ANSI/AAMI ES60601-1:2005/A2:2021 - Amendment 2:2021 to ANSI/AAMI ES60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment 2 (IEC 60601-1:2005 / A2:2020).

CSA C22.2 No. 60601-1-:14 (R2018) - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition + Amendment 1:2012)

CSA C22.2 No. 60601-1-6:11+AMD1:2015 (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)

CSA C22.2 No. 60601-1-6:11+AMD2:2021 - 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)

CAN/CSA-C22.2 No. 60601-1:14/AMD2:2022 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment 2

IEC 60601-1-6:2010/AMD1:2013 - AMENDMENT 1 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability - Edition 3.0

IEC 60601-1-6:2010 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

IEC 60601-1-6:2010/AMD2:2020 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability