Certificate of Compliance

Certificate: 70182237 **Master Contract:** 158114 (LR 100998)

Project: 80015449 **Date Issued:** 2019-10-17

Issued to: Delta Electronics, Inc.
3 Tung Yuan Rd,
Chungli Industrial Zone,
Taoyuan City, 3063
TAIWAN
Attention: Mr. Jerry Chang

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

C US

Issued by: Pat Leung
Pat Leung

PRODUCTS

CLASS 5311-28 - POWER SUPPLIES - Component Type - For Use in Medical Equipment/System
CLASS 5311-98 - POWER SUPPLIES - Component Type - For Use in Medical Equipment/System - Certified to US Standards

Medical Electrical Component Type Switching Power Supply, Model/Type: MEG-2K1A6, Connected to the AC mains supply by Appliance inlet or Primary terminal block.

Rated Input: 100-120V~, 50-60Hz, 15A-11A or 200-240V~, 50-60Hz, 12A-10A,
DC Rated Output:
1050W MAX. (SLOT1-SLOT6); 5Vsb/1A (when input 100-120V~),
2100W MAX. (SLOT1-SLOT6); 5Vsb/1A (when input 200-240V~),

See below tables for output rated voltage and rated current when different type of output module board be inserted into each slot of power supply.

Table 1: Single Slot Single Output Module

Customer Code	Output Module board name	Output V (d.c.)	Output current (A)
NU	If the slot does not provide with any output module		
A1	MEG-A252M06S AA	2	45
B1		2.4	45
C1		3	45
D1		3.3	45
E1		5	45
F1		5.5	45
G1		6	42
H1	MEG-A300M12S AA	8	25
I1		10	25
J1		12	25
K1		14	21.4
L1	MEG-A300M18S AA	15	20
M1		18	16.7
N1	MEG-A300M24S AA	20	15
O1		24	12.5
P1		28	10.7
Q1	MEG-A300M36S AA	30	10
R1		32	9.4
S1		36	8.3
T1		42	7.1
U1	MEG-A300M48S AA	48	6.3
V1		54	5.5
W1		60	5

Table 2: Single slot dual output module

Customer Code	Output Module board name	Output V (d.c.)	Output current (A)
D	MEG-A240M30D AA	3.3	5.0
E		5.0	5.0
F		5.5	5.0
G		6.0	5.0
H		8.0	5.0
I		10.0	5.0
J		12.0	5.0
K		14.0	5.0
L		15.0	5.0
M		18.0	5.0
N		20.0	5.0
O		24.0	4.0
P		28.0	4.0

Q		30.0	4.0

Table 3: Triple slot single output module

Customer Code	Output Module board name	Output V (d.c.)	Output current (A)
H2	MEG-A800M08S AA	8.0	100.0
I2	MEG-A1K2M12S AA	10.0	100.0
J2		12.0	100.0
K2		14.0	85.7
L2	MEG-A1K2M18S AA	15.0	73.3
M2		18.0	61.1
N2	MEG-A1K2M24S AA	20.0	53.0
O2		24.0	50.0
P2		28.0	42.8
Q2	MEG-A1K2M36S AA	30.0	33.3
R2		32.0	34.4
S2		36.0	33.3
T2		42.0	28.6
U2	MEG-A1K2M48S AA	48.0	25.0
V2		54.0	22.2
W2		60.0	20.0

Up to six sets connector (Slot 1 to Slot 6) provided in main board for installation various kind of output module board to provide different output voltage and current level as descriptive in above table.

1. Medical device protection against electric shock: Class I
2. Applied Part protection against electric shock: No applied part
3. Degree of protection against ingress of water or particulate matter: No degree of protection
4. Method of Sterilization: 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°C to 50°C, 5-95% RH, 700-1060hPa as specified by manufacturer.

APPLICABLE REQUIREMENTS

CSA Standards:

CSA C22.2-No. 60601-1:14	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005/(R) 2012, AND C1:2009 AND A2:2010(R) 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Subject to the following qualifications:

(1) A Medical Electrical Equipment 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 CSA C22.2-No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R) 2012, AND C1:2009 AND A2:2010(R) 2012 excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Usability (Clause 7.1.1 and 12.2), 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 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.
(5) Safety Risk Management: The equipment is a component type power supply. Risk management files according to ISO 14971 were not provided and not evaluated in this test report, risk management shall be considered as part of the end use medical product.
(6) The equipment is a component type power supply. Output of the PSU was not evaluated nor was it considered for direct contact to the patient; additional evaluation will be required in the end installation.
(7) The equipment is a component type PSU. The end-use equipment must be evaluated to determine compliance with the requirements of ISO 10993-1.
(8) The equipment is a component type power supply. The end-use equipment must be evaluated to determine compliance with the latest EMC requirements according to IEC 60601-1-2.
(9) The marking of letter “G” is provided adjacent to protective earth terminal. The terminal is intended for internal protective earth connection 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
80015449	2019-10-17	Update Report 70182237 to add customer code and revise name of output module boards; addition of new output modules, reversed air flow configuration and components changes.
70190946	2018-07-27	Update Report 70182237 to correct laminate & prepreg manufacturer typo for Output module board PCB in critical component.
70177339	2018-4-21	Original Certification.