Certificate of Compliance

Certificate: 80011819 **Master Contract:** 158114 (LR 100998)

Project: 80014698 **Date Issued:** 2019-10-14

Issued to: **Delta Electronics, Inc.**
3 Tung Yuan Rd,
Chungli Industrial Zone,
Taoyuan City, 32063
TAIWAN
Attention: Ms. Bonnie Liu

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: Alfred Lee

PRODUCTS

CLASS 5311-28 - POWER SUPPLIES - Component Type - For Use in Medical Equipment/System (Adopted IEC 60601-1 3rd edition)
CLASS 5311-98 - POWER SUPPLIES - Component Type - For Use in Medical Equipment/System - Certified to US Standards (Adopted IEC 60601-1 3rd edition)

Switching Power Supply (AC to DC Configurable Power Supply), Model MEG-1K2A4, Connected to the AC mains supply by Appliance inlet or Primary terminal block.

Rated Input:
100-120V~, 8.5A-8A 50-60Hz or 200-240V~, 7A-5.5A, 50-60Hz, Connected to the AC mains supply by Appliance inlet or Primary terminal block.

DC Rated Output:
640W MAX. (SLOT1-SLOT4); DC 5Vsb/2A (when input 100-120V~), or
1200W MAX. (SLOT1-SLOT4); DC 5Vsb/2A (when input 200-240V~)

See below table 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 (Single Slot Single output Module)	Output V (d.c.)	Output current (A)	Output watts (W)
A1	2	45	90
B1	2.4	45	108
C1	3	45	135
D1	3.3	45	149
E1	5	45	225
F1	5.5	45	248
G1	6	42	252
H1	8	25	200
I1	10	25	250
J1	12	25	300
K1	14	21.4	300
L1	15	20	300
M1	18	16.7	300
N1	20	15	300
O1	24	12.5	300
P1	28	10.7	300
Q1	30	10	300
R1	32	9.4	300
S1	36	8.3	300
T1	42	7.1	300
U1	48	6.3	300
V1	54	5.5	300
W1	60	5	300

Table 2: Single Slot Dual Output Module

Customer Code (Single Slot Single output Module)	Output V (d.c.)	Output current (A) (V1 or V2 Current)	Output watts (W) (V1 or V2 Power)
D	3.3	5.0	16.5
E	5.0	5.0	25.0
F	5.5	5.0	27.5
G	6.0	5.0	30.0
H	8.0	5.0	40.0
I	10.0	5.0	50.0
J	12.0	5.0	60.0
K	14.0	5.0	70.0
L	15.0	5.0	75.0
M	18.0	5.0	90.0
N	20.0	5.0	100.0
O	24.0	4.0	96.0

P	28.0	4.0	112.0
Q	30.0	4.0	120.0

Table 3: Triple Slot Single output Module

Customer Code (Single Slot Single output Module)	Output V (d.c.)	Output current (A)	Output watts (W)
H2	8.0	100.0	800
I2	10.0	100.0	1000
J2	12.0	100.0	1200
K2	14.0	85.7	1200
L2	15.0	73.3	1100
M2	18.0	61.1	1100
N2	20.0	53.0	1060
O2	24.0	50.0	1200
P2	28.0	42.8	1200
Q2	30.0	33.3	1000
R2	32.0	34.4	1100
S2	36.0	33.3	1200
T2	42.0	28.6	1200
U2	48.0	25.0	1200
V2	54.0	22.2	1200
W2	60.0	20.0	1200

Up to four sets connector (Slot 1 to Slot 4) 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: IPX0
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 to 95% RH, 700-1060hPa as specified by manufacturer.

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Project: 80014698 **Date Issued:** 2019-10-14

APPLICABLE REQUIREMENTS

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

Supplement to Certificate of Compliance

Certificate: 80011819 **Master Contract:** 158114 (LR 100998)

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
80014698	2019-10-14	Update report to include the following modifications: 1. Add new output modules (Add seven output modules with seven Transformers (T1)) 2. Add reversed air flow configuration 3. Add secondary side communication I/O board 4. Change output module board name to customer code 5. Revise mylar sheet shape for single slot output module 6. Add material for planar transformer (add two thermal cycling PCB sources)
80011819	2019-07-26	Original Certification.

Certificate of Compliance

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3 Tung Yuan Rd,
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Taoyuan City, 3063
TAIWAN

Attention: Ms. Bonnie Liu

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C US

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

Output Module board name	Output V (d.c.)	Output current (A)	Output watts (W)
MEG-A090M02S AA	2	45	90
MEG-A108MS02 AA	2.4	45	108
MEG-A135M03S AA	3	45	135
MEG-A149M03S AA	3.3	45	149
MEG-A225M05S AA	5	45	225
MEG-A248M06S AA	5.5	45	248
MEG-A252M06S AA	6	42	252
MEG-A200M08S AA	8	25	200
MEG-A250M10S AA	10	25	250
MEG-A300M12S AA	12	25	300
MEG-A300M14S AA	14	21.4	300
MEG-A300M15S AA	15	20	300
MEG-A300M18S AA	18	16.7	300
MEG-A300M20S AA	20	15	300
MEG-A300M24S AA	24	12.5	300
MEG-A300M28S AA	28	10.7	300
MEG-A300M30S AA	30	10	300
MEG-A300M32S AA	32	9.4	300
MEG-A300M36S AA	36	8.3	300
MEG-A300M42S AA	42	7.1	300
MEG-A300M48S AA	48	6.3	300
MEG-A300M54S AA	54	5.5	300
MEG-A300M60S AA	60	5	300

Up to four sets connector (Slot 1 to Slot 4) 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.

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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
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Project	Date	Description
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