Certificate of Compliance

Certificate: 70043860 **Master Contract:** 170351

Project: 70043860 **Date Issued:** 2015-09-09

Issued to: **Bel Fuse Inc.**
206 Van Vorst St
Jersey City, New Jersey 07302
USA
Attention: Editha S. Vergara

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: *Bradley Clasby*
Bradley Clasby, AScT

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 Std

Component Power Supply, Models MBC600-1012G, MBC600-1024G and MBC600-1048C, input rated 100-250 Vac, 50/60 Hz, 8.0-4.0 A or 120-240 V dc, 7.0-2.5 A; Outputs rated as follows:

Model Number	Output Ratings			Total combined load (@ 50 °C ambient)
	V1	Vsb	Vfan	
MBC600-1012G	12 V, 50 A	5 V, 1.0 A	12 V, 1.0 A	617 W (300 LFM cooling) or 420 W (convection cooling)
MBC600-1024G	12 V, 25 A			
MBC600-1048G	12 V, 12.5 A			

Notes:
1. Output power is de-rated linearly to 50% at 70 °C ambient for the V1 & Vfan outputs.
2. Medical device protection against electric shock: Class I.
3. Applied Part protection against electric shock: No applied part.
4. Degree of protection against ingress of water or particulate matter: No degree of protection.
5. Method of Sterilization: None.
6. Suitability for use in an Oxygen Rich Environment: N/A – Component.

7. Suitability to use Medical device in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: N/A – Component.
8. Mode of operation: Continuous.

APPLICABLE REQUIREMENTS

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 + A1:2012-07, MOD)
ANSI/AAMI ES60601-1:2005/(R)2012, AND C1:2009 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. The equipment covered in this report is a component intended to be installed in the end ME system, which will be used in a hospital or related health care facility. Suitability of the combination is to be determined by CSA Group.
2. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:
   - Clause 7.5 (Safety Signs),
   - Clause 8.5.5 (Defibrillation-Proof Applied Parts),
   - Clause 7.9 (Accompanying Documents),
   - Clause 9 (Mechanical Hazard),
   - Clause 10 (Radiation),
   - Clause 14 (PEMS),
   - Clause 16 (ME Systems), and
   - Risk Management was excluded from this investigation.

3. Risk Controls / Engineering Considerations for component power supply: For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory. When installed in an end-product consideration must be given to the following:

   - 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 (F101, F102).
   - 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.
   - Power Supply tested for an environment: -25 to 70 ºC, 10 – 90% RH, 3048 m elevation. 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 routing of wires away from sharp edges as part of the power supply.
- Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner.
- End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted.
- 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.

In addition the following specific conditions shall be taken into consideration:

1. Reliable connection to protective earth shall be provided in the end use installation.
2. Isolation means internal to equipment were evaluated for compliance with MOPP requirements.
3. Output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
4. Complete fire enclosure shall be provided in the end use installation.
5. Spacings have been evaluated for a maximum operating altitude of 3048 m (correction factor per IEC 60664 applied).
6. Input/Output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of internal wiring inside the end product.
7. Suitable disconnect device, to disconnect the equipment from mains power before servicing, shall be provided in the end use product.
8. Evaluated for connection to both AC and DC power with a branch circuit protector rated 20 A.
9. Input common-mode inductors and gate drive transformer use insulation rated 130 °C. The isolation transformers employ UL Recognized Insulation Systems as described in the list of critical components.
10. The power supply was evaluated as per manufacturer's specifications, for use in the ambient temperature of max 50 °C @ full load, with forced air cooling provided by a 300 LFM external fan blowing across the input to output. Output power is limited to 420 W with convection cooling. Output power is linearly derated for ambient temperatures above 50 °C up to 70 °C. Consideration shall be given to the fan cooling in the testing within the end use ME equipment.

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
70043860	2015-09-09	Medical Grade Power Supply, Model MBC-600-1012G, MBC600-1024G, MBC600-1048G.