



Product Service

CERTIFICATE

No. B 057396 0350 Rev. 01

Conditions of Acceptability:

When installing the equipment, all requirements of the standards and the manufacturer's specifications must be met.

The models require:

- A suitable fire enclosure shall be provided in the end use equipment.
- Proper bonding to the end-product main protective earthing termination is: required when the power supply is used in a Class I end product. The power supply will be considered Class II only when protection against electric shock does not rely on 1 Method of Protection of Insulation.
- The power supply units may provide double pole fusing, proper warning shall be provided at end product.
- Units were evaluated for use with 10 cfm external airflow. The need of cooling shall be determined as part of the end product.
- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary- Earthed Dead Metal: 240 Vrms, 340 Vpk and Primary-SELV: 240 Vrms, 340 Vpk.
- The following input terminals/connectors must be connected to the end-product supply neutral: CN1.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage test shall be considered in the end product application.
- Models provided with suffix SF only provided with one line side fuse. Consideration should be made in the end-use product to determine the need of double pole fusing.
- The suitability of the breaking capacity of the fuse per Clause 8.11.5 shall be verified in the end product.
- This power supply has been evaluated as a continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- Protective earthing testing shall be conducted in the end product application.
- Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems).
- The product was not investigated to the following standards or clauses: Biocompatibility (ISO 10993-1), Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 60601-1-2).

Tested according to: EN 60601-1:2006/A12:2014

Production Facility(ies): 071712, 089850, 003227