CERTIFICATE OF COMPLIANCE

Certificate Number	2021-04-29; 2021-11-30 (A1/C); 2023-11-06 (A2); 2024-01-19 (A3)-E146893
Report Reference	E146893-D1035-1/A3/C0-UL
Date	2021-04-29; 2021-11-30 (A1/C); 2023-11-06 (A2); 2024-01-19 (A3)
Issued to:	XP POWER L L C
Applicant Company:	340 Commerce, Suite 100 Irvine, CA 92602 UNITED STATES
Listed Company:	Same as Applicant
This is to certify that representative samples of	Component Switching Power Supply GCS250PSxxyy (where xx can be any number between 12 and 56 and yy is "-C", "-TF", "-EF" or blank; all "-" considered optional; may also be provided with additional suffix "SF", "S", "R" or "L") and 102451-XX, 102493-XX (where X may be any alphanumeric character or blank denoting manufacturer's version control number and it controls minor changes that do not affect safety aspects (construction and critical components))
	Have been investigated by UL in accordance with the component requirements in the Standard(s) indicated on this Certificate. UL Recognized components are incomplete in certain constructional features or restricted in performance capabilities and are intended for installation in complete equipment submitted for investigation to UL LLC.
Standard(s) for Safety:	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14
Additional Standards:	None
Additional Information:	See the UL Online Certifications Directory at https://iq.ulprospector.com for additional information.

This Certificate of Compliance does not provide authorization to apply the UL Recognized Component

Bruce Mahrenholz, Director North American Certification Program

UL LLC

Mark. Only the UL Follow-Up Services Procedure provides authorization to apply the UL Mark.

Only those products bearing the UL Recognized Component Mark should be considered as being UL Certified and covered under UL's Follow-Up Services.

Look for the UL Recognized Component Mark on the product.

Bruce Mahrenholz, Director North American Certification Program

UL LLC

Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8
Complementary CCNs:	
Product:	Component Switching Power Supply
Model:	GCS250PSxxyy (where xx can be any number between 12 and 56 and yy is "-C", "-TF", "-EF" or blank; all "-" considered optional; may also be provided with additional suffix "SF", "S", "R" or "L") and 102451-XX, 102493-XX (where X may be any alphanumeric character or blank denoting manufacturer's version control number and it controls minor changes that do not affect safety aspects (construction and critical components))
Rating:	Input: 100-240 Vac, 50/60 Hz, 3A Output: See Model Differences for details
Applicant Name and Address:	XP POWER L L C 340 Commerce, Suite 100 Irvine, CA 92602, UNITED STATES

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability as applicable.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Longjie Zhang/Project Handler

Reviewed by: James Gochman/Project Reviewer

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

i. **Part AC** details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.

ii. **Part AE** details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.

iii. **Part AF** details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Product Description

The model covered in this report is a component power supply intended for use in Medical Electrical Equipment. It is an open frame power supply intended for building-in Class I or Class II end-products. The Double insulated symbol (symbol 9 of Table D.1 - IEC 6017-5172) is optionally provided. Earthing (ground) symbol (Symbol 6 from Table D.1- IEC 60417-5017) may only be provided for Class I power supplies. Refer to the Report Modifications page for any modifications made to this report.

Model Differences

All models in the Model GCS250PSXX series are identical with exception to the Mains Transformer, T1, shape of Heatsink (SEC) and secondary components/circuitry that allow for different output voltage ratings. See below for minor variations within the series.

Models GCS250PS12 to GCS250PS18 are identical to models GCS250PS24 to GCS250PS56 except for secondary output circuitry and secondary heatsink.

Models GCS250PS24 to GCS250PS36 are identical to models GCS250PS48 to GCS250PS56 except for secondary heatsink.

See below for Model Ratings:

Model GCS250PS12: Output Rated: 10.1 Vdc - 13.5 Vdc, 18.7 A Max., 225 W Max.
Model GCS250PS15: Output Rated: 13.6 Vdc - 17 Vdc, 15 A Max., 225 W Max.
Model GCS250PS18: Output Rated: 17.1Vdc - 21 Vdc, 13.9A Max, 250V Max
Model GCS250PS24: Output Rated: 21.1 Vdc - 26 Vdc, 10.4 A Max., 250 W Max.
Model GCS250PS28: Output Rated: 26.1 Vdc - 31 Vdc, 8.9 A Max., 250 W Max.
Model GCS250PS33: Output Rated: 31.1 Vdc - 33 Vdc, 7.6 A Max., 250 W Max.
Model GCS250PS36: Output Rated: 33.1 Vdc - 42 Vdc, 6.9 A Max, 250 W Max.
Model GCS250PS48: Output Rated: 42.1 Vdc - 54 Vdc, 5.2 A Max., 250 W Max.
Model GCS250PS56: Output Rated: 54.1 Vdc - 63.2 Vdc, 4.5 A Max., 250 W Max.

Model 102451-XX is identical to existing Model GCS250PS28yy with the exception of extended casing to support an IEC inlet and it has an operating maximum ambient of 60 degrees C with forced air cooling only.

Model 102493-XX is identical to excisting Model 102451-XX except model designation

Model 102451-XX and 102493-XX: Output Rated: 26.7 Vdc, 9.36A Max, 250W Max.

Units provided with suffix "C" is provided with cover.
Units provided with suffix "TF" is provided with top fan.
Units provided with suffix "EF" is provided with end fan.

Units provided without suffix "C", "TF" or "EF" is open frame (without cover).
Units provided with additional suffix "SF" to indicate single pole fusing.
Units provided with additional suffix "S" to indicate screw terminal block.
Units provided with additional suffix "L" to indicate fly leads.
Units provided with suffix “R” is remote inhibit

See Enclosure - Miscellaneous for max Power Outputs based on model, ambient, and forced air cooling.

Additional Information
The Marking Plate provided is representative of all models covered under this Report.

Reissue (Project #4788808600, Reissue of report E146893-D27-CB-1-Amendent-1 (CBTR 4786488108-4) was reissued on 2019-01-08 with the following changes:

1. Added alternate component, End Fan (SELV) - Optional - for Models with - EF Suffix was added: Delta Electronics Inc, EFB0412MD, Rated 12Vdc,max. 0.10A,max. (7 CFM)

No additional testing was deemed necessary to evaluate the models covered under this Report to IEC 60601-1, Edition 3 with Am.1 based on previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams, etc. conducted under separate CB Scheme investigation to IEC 60601-1, 3rd ed issued under CBTR No. E146893-A49-CB-1, CBTC No. US-22757-UL.

CB Test certificates for components are included in Licenses Enclosure. In accordance with the current rules of CB Scheme, CB Test certificate is effective for 3 years. Recognizing NCB may challenge the CBTC when certificates are more than 3 years old.

When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

The following tests were selected as representative of the test program applicable to the models covered by this CBTR: 8.4.3 Voltage or Charge Limitation. These tests have been witnessed for models selected as representative of the product family covered by this report and of the applicable test program.

Technical Considerations

- The product was investigated to the following additional standards: None
- The following additional investigations were conducted: EN 60601-1:2006 + A1:2013 + A12:2014
- 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)
- The following accessories were investigated for use with the product: None
- The degree of protection against harmful ingress of water is: Ordinary

  The mode of operation is: Continuous

  The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No

  The equipment has been evaluated for use in 50°C ambient at Full Rated Output and 50% of the Rated Output in 70°C ambient. (See De-rating Curve, Enclosure Rating Table for more detail) with exception adding models 102451-XX and 102493-XX

  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 is Classified only to the following hazards: Shock, Fire, Casualty

Power Supply was considered Overvoltage Category II (OVCII)

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. When installed in an end-product, consideration must be given to the following:

- When installed in an end-product, consideration must be given to the following:
  - The component shall be considered for compliance with the Marking (clause 7) and Separation (clause 8) requirements as part of the end use application evaluation.
  - Repeat of leakage current testing and consideration of non-frequency weighted leakage current (clause 8.7.3e) to be considered as part of 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).
  - The end product shall ensure that the requirements related to accompanying documents, clause 7.9, are met.
  - The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
  - The output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.
  - The Dielectric Strength Test conducted on this power supply was based upon a maximum working voltage of 340 Vpk, 232 Vrms for Primary-Earthed Dead Metal; 320Vpk, 180Vrms from Primary-secondary.
  - Power supply provides the following MOPP (means of patient protection): two MOPP based upon a working voltage 240 Vrms, 320 Vpk between Primary to Secondary, one MOPP based upon a working voltage 240Vrms, 340 Vpk between Primary and Earth/Enclosure, one MOPP based upon a working voltage 250 Vrms between secondary and earthing trace or chassis for BF output consideration.
  - Cleaning test shall be considered as part of end product evaluation
  - The need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation.
  - The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
  - The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY2 insulation system with the indicated rating greater than Class A (105°C): L1, L4 and T1 (Class F, 155°C)
  - The PWB is rated 130°C.
  - For Class I applications: Unit to be properly bonded to end product main protective earth.
  - Units provided with single fuse in Line side, end product to determine the need for additional double pole fusing as part of the end product.
  - Unit has been subjected to 5 day humidity condition test at 93%, 40°C.
  - When installed in a Class I end product, the power supply shall be mounted in a manner that provides, at a minimum, 3.2 mm Clearance/4 mm Creepage between the primary sides of power supply and protectively earthed accessible conductive parts. In addition, when installed in a Class I end product, the protective bonding terminal of the power supply shall be reliably connected to the main protective earthing terminal of the end product.
  - When installed in a Class II end product, the power supply shall be mounted in a manner that provides sufficient clearance and creepage distance between the hazardous parts and accessible conductive parts.
  - Proper bonding to the Class I end-product main protective earthing termination is required (via mounting holes on the PCB), unless for Class II applications. For Class II applications the primary side mounting pads are isolated from accessible conductive chassis by Reinforced Insulation
  - Forced-air cooling with cover at 7 CFM shall be provided with the end product in order to achieve maximum power output.

- Device has been evaluated for a 5000 m altitude.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage current (clause 8.7.3e) to be considered as part of the end product.
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- The model 102451 may be equipped with an optional thermal switch which will shutdown the power supply if temperatures in the power supply exceed 110°C suitability shall be considered as part of the end product installation.

Markings and instructions	
Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Serial number or lot or batch identifier	Serial number or lot or batch identifier
Date of manufacture or use by date	Date of manufacture or use by date
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts

Special Instructions to UL Representative
N/A

Production-Line Testing Requirements			
Required	Test	Model/Part Exempt from Test	Additional Details
Yes	Grounding Continuity	None	---
Yes	Dielectric Voltage Withstand	None	---
No	Patient Circuit Dielectric Voltage Withstand	---	---
Solid-State Components			
The following solid-state components that can be disconnect from the remainder of the circuitry during either Dielectric Voltage Withstand Test:		Parts to be disconnected for test:	Specific Test:
		None	---
		---	---
		---	---
		---	---
		---	---

Sample and Test Specifics for Follow-Up Tests at UL			
The following tests shall be conducted in accordance with the Generic Inspection Instructions			
Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
N/A	---	---	---
N/A	---	---	---
N/A	---	---	---
N/A	---	---	---
N/A	---	---	---

N/A	---	---	---
N/A	---	---	---
N/A	---	---	---
N/A	---	---	---
N/A	---	---	---