CERTIFICATE OF COMPLIANCE

Certificate Number	2019-05-21; 2019-07-20 (A1/C0); 2019-10-18 (A2/C0)-E146893
Report Reference	E146893-D1038-1/A2/C0
Issue Date	2019-05-21; 2019-07-20 (A1/C0); 2019-10-18 (A2/C0)
Issued to:	XP Power LLC
Applicant Company:	15641 Red Hill Ave, Suite 100 Tustin, CA 92780 USA
Listed Company:	Same as Applicant
This is to certify that representative samples of	Build in power supply ECS100USxx-By (where xx can be any number between 12 and 48 designating the output voltage, y can be blank or SF). Models with suffix SF designate single fuse. ECS100US12-B-XE0399 Have been investigated by UL in accordance with the Standard(s) indicated on this Certificate.
Standard(s) for Safety:	IEC 60601-1 :2005 +A1 :2012
Additional Standards:	None
Additional Information:	See the UL Online Certifications Directory at www.ul.com/database for additional information.

Only those products bearing the UL Certification Mark should be considered as being covered by UL's Certification and Follow-Up Service.

Recognized components are incomplete in certain constructional features or restricted in performance capabilities and are intended for use as components of complete equipment submitted for investigation rather than for direct separate installation in the field. The final acceptance of the component is dependent upon its installation and use in complete equipment submitted to UL LLC.

Look for the UL Certification Mark on the product.

This is to certify that representative samples of the product as specified on this certificate were tested according to the current UL requirements.

Bruce Mahrenholz, Assistant Chief Engineer, Global Inspection and Field Services, UL LLC
Joseph Hosey, General Manager, Director of Sales – Canada, UNDERWRITERS LABORATORIES OF CANADA INC.

Helena Y. Wolf, Director, Global Market Access Operations, UL LLC

Description

UL TEST REPORT AND PROCEDURE

Standard:	IEC 60601-1 :2005 +A1 :2012
Certification Type:	Component Recognition
CCN:	QQHM2/QQHM8
Complementary CCNs:	QQHM8
Product:	Build in power supply
Model:	ECS100USxx-By (where xx can be any number between 12 and 48 designating the output voltage, y can be blank or SF). Models with suffix SF designate single fuse. ECS100US12-B-XE0399
Rating:	Models ECS100USxx-By: Input Rated: 100-240 V~, 1.9A, 50/60 Hz Output Rated: See Enclosure - Miscellaneous 7-01 for maximum output details. Model ECS100US12-B-XE0399: Input Rated: 100-240 V~, 1.9A, 50-60 Hz Output Rated: 12Vdc, 8.34A
Applicant Name and Address:	XP Power LLC 15641 Red Hill Ave, Suite 100 Tustin, CA 92780, USA

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: Mitchell McGarry, Project Handler Reviewed by: Ned Devine, 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

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 -product. The need for the additional testing and evaluation shall be determined in the end product evaluation.
Refer to the Report Modifications page for any modifications made to this report.

Model Differences

All models in the Model ECS100USxx-By series are identical with exception to the Mains Transformer (T1) and minor secondary components that allow for different output voltage ratings. Models with suffix SF designate single fuse in line side.

Model ECS100US12-B-XE0399 is similar to Model ECS100US12-B series except for a larger PWB and addition of Metal Oxide Varistor (VDR2), Ceramic Capacitors (C20, C21), and Secondary Capacitor (C11).

Additional Information

This report is a reissue of CB Report Reference # 4786488108-2 and CB Certificate # US-23760-A3-M1-UL. All applicable testing was conducted under previous investigation.
Manufacturer submitted a sample of Model ECS100US12-B-XE0399 and limited testing is considered necessary to add alternate IC (Q1) (PRI) rating of 16A.
Following testing is considered necessary to add alternate Q1 rated 600V, 16A to the report. Test tables and critical components table is revised accordingly.
1. Leakage Current Test
2. Dielectric Voltage Withstand Test
3. Abnormal Operation Test
No testing is considered necessary to revise Essential Performance to N/A based on review of risk management files.

Technical Considerations

- The product was investigated to the following additional standards: None
- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Biocompatibility, PESS, EMC, Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product: None
- None

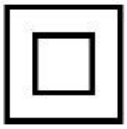
Engineering Conditions of Acceptability

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.
  Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end use product shall ensure that the power supply is used within its ratings.
  Proper bonding to the end-product main protective earthing termination is required. Grounding continuity shall be conducted in the end product.
  Repeat of leakage current testing and consideration of non-frequency weighted leakage current (clause 8.7.3) 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 following secondary output circuits are at hazardous energy levels: Output
  The input/output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.
  The end-product Electric Strength Test is to be based upon a maximum working voltage of Primary-SELV: 240 Vrms, 541Vpk; Primary to Ground: 244Vrms, 353Vpk.
  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.
  Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
  Fuse replacement marking to be provided near the fuse holder as part of the end product.
  Magnetic devices T1, L1, L2 employ a Class F (155°C) insulation system.
  PWB is rated 130 deg. C.
  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 products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
  This power supply was evaluated with Two MOPP between primary and secondary; One MOPP primary and Earth; One MOPP between secondary and Earth for Class I application; Functional Insulation between secondary and floated earth trace for class II application
  Compliance of adequate breaking capacity of the fuse per Clause 8.11.5 to be verified when installed in an end product.
  The need for Marking Durability and Marking Legibility Testing to be considered as part of the end product installation
  A single input current rating is provided over the entire 100-240Vac voltage range. The end product evaluation is to determine the acceptability.
  When installed in a Class I end product, the power supply shall be mounted in a manner that provides, at a min. 2.5 mm Clearance between the primary side of the 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, on insulating posts, in a manner that provides, at a min. 5.1 mm Clearance between the primary side of the power supply and any accessible conductive parts.
  Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
  Units with SF suffix are provided with only one fuse in the line side. The need for additional fusing shall be determined as part of the end-product evaluation.
  The equipment has been evaluated for use in a maximum ambient of 50°C for 100% load at forced air cooling condition and 80% load at convection cooling condition; evaluated for use in a maximum ambient of 70°C for 50% load at forced air cooling condition and 40% load at convection cooling condition. 10CFM used for forced air cooling evaluation. (See De-rating Curve, Miscellaneous

Enclosure 7-05).

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
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Supply Frequency	Rated frequency range in hertz
Class II equipment	For class II models only 
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.

Special Instructions to UL Representative
None

Production-Line Testing Requirements		
Test Exemptions - The following models are exempt from the indicated test		
Test	Exemption Specifics	Details
Grounding Continuity	The following models are exempt from the indicated test:	Class II models
Dielectric Voltage Withstand	The following models are exempt from the indicated test:	None (Not Exempt)
Patient Circuit Dielectric Voltage Withstand	The following models are exempt from the indicated test:	All models (Exempt)
Solid-State Components	The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	All models (Exempt)

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
None	NA	NA	NA