CERTIFICATE OF COMPLIANCE

Certificate Number 2016-09-09-E146893

E146893-D1013-1/A0/C1-ULCB Report Reference

> **Issue Date** 2016-09-09

XP Power LLC Issued to:

Applicant Company: 15641 RED HILL AVE., STE 100

TUSTIN, CA 92780 USA

Same as Applicant **Listed Company:**

Switching Power Supply This is to certify that

representative samples of ECS65USXX where XX is any number between 12-48

designating output voltage, may also be provided with suffix SF

and optional B or C with or without -.

Have been investigated by UL in accordance with the

Standard(s) indicated on this Certificate.

ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 Standard(s) for Safety:

NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)

Additional Standards:

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.

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Description

UL TEST REPORT AND PROCEDURE

Standard: ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012) **Certification Type:** Component Recognition QQHM2 / QQHM8 CCN: **Complementary CCNs:** Product: Switching Power Supply Model: ECS65USXX where XX is any number between 12-48 designating output voltage, may also be provided with suffix SF and optional B or C with or without -. Input: 100-240 Vac, 1.2 A, 50/60 Hz; C option: 160-240 Vac, 1.2A, 50/60Hz Rating: Output: See Model Differences for details **Applicant Name and** XP Power LLC 15641 RED HILL AVE., STE 100 Address: 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.

Haydee Gonzalez / Project Reviewed by: Ahmad Daoudi / Project Prepared by:

Handler Reviewer Page C-31 of C-42 Report No.: E146893-D1013-1/A0/C1-

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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 -
 - 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

Products covered are open frame power supplies intended for building-in to be used with Medical Electrical Equipment. Units are intended for used with Class I or Class II end-products. Refer to the Report Modifications page for any modifications made to this report.

Model Differences

All models in the Model ECS65USXX series are identical with exception to the Mains Transformer, T1, and minor secondary components that allow for different output voltage ratings. Model ECS65US12BC is identical to Model ECS65USXX series except for cover kit. See below for Model Ratings for up to 50°C ambient:

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Model ECS65US12: Output Rated: 10.1 Vdc to 13.5 Vdc, 5.4 A Max (65W Max) Model ECS65US15: Output Rated: 13.6 Vdc to 17 Vdc, 4.3 A Max (65 W Max) Model ECS65US18: Output Rated: 17.1 Vdc to 21 Vdc, 3.4 A Max (65 W Max) Model ECS65US24: Output Rated: 21.1 Vdc to 26 Vdc, 2.7 A Max (65 W Max) Model ECS65US28: Output Rated: 26.1 Vdc to 31 Vdc, 2.3 A Max (65 W Max) Model ECS65US33: Output Rated: 31.1 Vdc to 33 Vdc, 2.0 A Max (65 W Max) Model ECS65US36: Output Rated: 33.1 Vdc to 42 Vdc, 1.8 A Max (65 W Max) Model ECS65US48: Output Rated: 42.1 Vdc to 54 Vdc, 1.4 A Max (65 W Max)
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Model ECS65US12-BC: Output Rated: 10.1 Vdc to 13.5 Vdc, 4.33 A Max (52 W Max)

See Enclosures Misc-01 and Enclosure Misc-02 for de-rating curve for ambient temperatures up to 70°C.

Suffix "-SF" indicates single fuse provided in the line side of the primary.

Suffix "-B" indicates unit provided with optional EMI Inductor, L2.

Suffix "C" indicates unit provided with optional cover kit.

Additional Information

This report is a reissue of CBTR Ref. No. 4786488107-20111012 issued on 2016-01-20 (E146893-D37), CB Test Certificate Ref. No. US-23822-A3-UL. Based on previously conducted testing and the review of product construction, only limited tests were deemed necessary to add alternate model ECS65US12-BC.

Manufacturer to provide up to date IEC Licensed for component licenses greater than 3 years upon request.

This report is a correction of CBTR Ref. No. E146893-D1013-1/A0/C0-ULCB issued on 2016-08-31, CB Test Certificate Ref. No. US-28446-UL. All the test information is referred to the previous reports.

Technical Considerations

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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: Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7, 8.7.4.9, 8.9.1.15; Battery related clauses: 7.3.3, 15.4.3; Hand Control related clauses: 8.10.4; Oxygen related clauses: 11.2.2; Fluids related clauses: 11.6.2 11.6.4; Sterilization clause: 11.6.7; Biocompatibility Clause: 11.7 (ISO 10993); Motor related clauses: 13.2.13.3, 13.4; Heating Elements related clause: 13.2; Flammable Anaesthetic Mixtures Protection: Annex G
- 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 installed in compliance with the Marking (clause 7) and Separation (clause 8) requirements of the end use application.
- Repeating leakage current testing and consideration of non-frequency weighted leakage current test (Clause 8.7.3e) shall be considered in the end product application.
- This power supply was evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth/Secondary Reference Conductor; and One MOPP between Secondary and Earth/ Secondary Reference Conductor.
- 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 should 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 non-hazardous energy levels: All outputs
- The output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.
- The maximum investigated branch circuit rating is: 20 A
- The Dielectric Withstand Voltage Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 359 Vpk, 244 Vrms; Primary-SEC: 588 Vpk, 249 Vrms.
- When installed in a Class I end product, the power supply shall be mounted in a manner that
 provides, at a minimum, 2.5 mm Clearance/4 mm Creepage between the primary side 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, on insulating posts, in a manner that provides, at a min. 5 mm Clearance/8 mm Creepage between the power supply and any accessible conductive parts.
- An investigation of the protective bonding terminal has: Not been conducted.
- For Class I application: Protective bonding testing shall be considered in the end product application.
- Primary side heat sinks are floating and considered live. They should not be accessible in the endproduct.
- 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-L3 and T1 are min. Class F (155°C).
- Printed Wiring Board rated 130°C.

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• Cleaning test to 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.
- Unit provided with additional suffix "-SF" are provided with only one fuse in the line side. Consideration for the need for additional fusing to be provided as part of the end product.

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Markings and instructions				
Clause Title	Marking or Instruction Details			
Company identification	XP Power LLC			
Model	ECS65USXX (where XX is any number between 12-48 designating output voltage), may also be provided with suffix "SF" and/or "B", with or without "-"			
Serial number or lot or batch identifier	Eight alpha numeric characters (A BB CC DDD where A = factory code; BB = year; CC=week; DDD = serial number)			
Date of manufacture or use by date	Provided as part of the serial number.			
Supply Connection	100 - 240 Vac, 1.2 A			
Alternating current	\sim			
Supply Frequency	50/60 Hz			
Output	See Model Differences for details			

Special Instructions to UL Representative

None

Plastic Enclosure or

Part

Production-Line Testing Requirements							
<u>Test Exemptions</u> - The following models are exempt from the indicated test							
Test	Exemption Specifics	Details					
Grounding Continuity	The following models are exempt from the indicated test:	Exempt					
Dielectric Voltage Withstand	The following models are exempt from the indicated test:	Not Exempt (test)					
Patient Circuit Dielectric Voltage Withstand	The following models are exempt from the indicated test:	Exempt					
Solid-State Components	The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	Exempt					
Sample and Test Specifics fo	<u> </u>						

Sample(s)

Test Specifics

The following tests shall be conducted in accordance with the Generic Inspection Instructions

Test

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None	NA	NA	NA	