CERTIFICATE OF COMPLIANCE

Certificate Number	20140227-E188913
Report Reference	E188913-A27-UL
Issue Date	2014-FEBRUARY-27
Issued to:	TRACO ELECTRONIC AG SIHLBRUGGSTRASSE 111 CH-6340 BAAR SWITZERLAND
This is to certify that representative samples of	Component - Power Supplies, Medical and Dental AC/DC Power Module, TMM 24aX, TMM 24bX (where a can be 105, 109, 112, 115, 124; b can be 212, 215; X can be C or blank)
	Have been investigated by UL in accordance with the Standard(s) indicated on this Certificate.
Standard(s) for Safety:	ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
Additional Information:	See the UL Online Certifications Directory at www.ul.com/database for additional information

Only those products bearing the UL Recognized Component Marks for the U.S. and Canada should be considered as being covered by UL's Recognition and Follow-Up Service and meeting the appropriate U.S. and Canadian requirements.

The UL Recognized Component Mark for the U.S. generally consists of the manufacturer's identification and catalog number, model number or other product designation as specified under "Marking" for the particular Recognition as published in the appropriate UL Directory. As a supplementary means of identifying products that have been produced under UL's Component Recognition Program, UL's Recognized Component Mark: , may be used in conjunction with the required Recognized Marks. The Recognized Component Mark is required when specified in the UL Directory preceding the recognitions or under "Markings" for the individual recognitions. The UL Recognized Component Mark for Canada consists of the UL Recognized Mark for Canada: and the manufacturer's identification and catalog number, model number or other product designation as specified under "Marking" for the particular Recognition as published in the appropriate UL Directory.

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 Recognized Component Mark on the product.

William R. Carney

William R. Carney, Director, North American Certification Programs

UL LLC

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	AC/DC Power Module
Model:	TMM 24aX, TMM 24bX (where a can be 105, 109, 112, 115, 124; b can be 212, 215; X can be C or blank)
Rating:	Input: 100-240Vac, 60/50 Hz, 0.6A- 0.3A Output: Models Output TMM 24105X 5.0 V dc, 3.0 A TMM 24109X 9.0 V dc, 2.666 A TMM 24112X 12 V dc, 2.0 A TMM 24115X 15 V dc, 1.6 A TMM 24124X 24 V dc, 1.0 A TMM 24212X +/-12 V dc, +/-1.0 A TMM 24215X +/-15 V dc, +/-0.8 A
Applicant Name and Address:	TRACO ELECTRONIC AG SIHLBRUGGSTRASSE 111 CH-6340 BAAR SWITZERLAND

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.

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

Prepared by: Sharon Hsu Reviewed by: Chenchen Lee

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 unit is an open frame power supply, and all electrical components inside power supply are mounted on PWB and insulating compound completely fills the casing of power supply.

The unit is intended to produce varieties of output voltage at max ambient temperature 65 degree C. The power supply can be employed to operate at ambient 75 degree C, but the max output load is derated to 50% max output loading; at ambient 80 degree C, but the max output load is derated to 25% max output loading.

The risk management requirements of the standard were not addressed.

Model Differences

Models TMM 24aX, TMM 24bX (where a can be 105, 109, 112, 115, 124; b can be 212, 215; X can be C or blank)
"a" can be 105, 109, 112, 115, 124, denotes single output voltage 5V, 9V, 12V, 15V and 24V.
"b" can be 212, 215, denotes dual output voltage +12V and -12V; +15V and -15V;
"X" can be C, denote unit with terminal block; blank denote unit without terminal block.

Model TMM 24aC, TMM 24bC are similar to model TMM 24a, TMM 24b except enclosure used with terminal block

Output:

Models	Output
TMM 24105X	5.0 V dc, 3.0 A
TMM 24109X	9.0 V dc, 2.666 A
TMM 24112X	12 V dc, 2.0 A
TMM 24115X	15 V dc, 1.6 A
TMM 24124X	24 V dc, 1.0 A
TMM 24212X	+/-12 V dc, +/-1.0 A
TMM 24215X	+/-15 V dc, +/-0.8 A

Technical Considerations

- Classification of installation and use : AC/DC Power Module for building in
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : R/C component, to be defined in the end product
- Mode of operation : Continuous
- Supply connection : R/C component, terminal block or pin
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: IEC 60601-1:2005; , EN 60601-1: 2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance); , CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada); , ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States); , ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012; , IEC 60601-1:2005; CORR1:2006;CORR2:2007;AMD1:2012, EN 60601-1:2006/A1:2013,

- The product was not investigated to the following standards or clauses:: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- 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

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:

- This power supply has been judged on the basis of the required creepage and clearances in the First Edition of the Standard for Medical Electrical Equipment, ANSI/AAMI ES60601-1, Sub clause 8.9.
- This power supply has been evaluated as a Class II, 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. An additional evaluation shall be made if the power supply is intended for use in other than Class II equipment.
- Consideration shall be given to measuring the temperatures on power electronic components and transformer windings when the power supply is installed in/with the end use equipment. Transformer, T1, employs a Class B (130) insulation system.
- Considerations to the applied parts requirement, to be conducted as end product.
- 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.
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The power supply was evaluated as 2 MOPP between Primary and Secondary. Transformer T1 with triple insulation wire in secondary, core was treated as Primary.
- The insulating compound completely fills the casing of power supply, and minimum 0.4 mm distances through insulation to provide required creepage and clearance.
- Temperature, Leakage Current, Dielectric Voltage Withstand, Voltage or Charge Limitation, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- The max ambient temperature 65 degree C. The power supply can be employed to operate at ambient 75 degree C, but the max output load is derated to 50% max output loading; at ambient 80 degree C, but the max output load is derated to 25% max output loading.
- 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 reference voltage for Dielectric Voltage Test in End Product: 281Vrms, 488Vpk for T1.
- A suitable Mechanical, Electrical and Fire enclosure shall be provided in the end use product.
- End product Risk Management Process to include consideration of requirements, specific to the Power Supply.
- 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.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat.

- 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 the movement of conductors as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and 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 as part of the power supply.
- For models TMM 24aC, TMM 24bC with terminal block, the insulation distance (2MOPP) between primary small PCB to plastic case is insufficient and end product shall provide suitable electrical enclosure and evaluate CR/CL.
- Overcurrent releases of adequate breaking capacity must be employed in the end product.

Additional Information

The risk management requirements of the standard were not addressed.

Additional Standards

The product fulfills the requirements of: EN 60601-1: 2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance); CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada); ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States); ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012; IEC 60601-1:2005; CORR1:2006;CORR2:2007;AMD1:2012 EN 60601-1:2006/A1:2013

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

Special Instructions to UL Representative

N/A