

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:	Other
Model:	ZMS100-X/E/T/J or CUS100MA-X/E/T/J Where: -X = Output Voltage as detailed in the Output Parameters tables below. /E = Curve B radiated for emc /T = Earth fast-on terminal not fitted /J = JST input and/or output connectors fitted Type references may be prefixed by SP and/or NS # followed by / or - (where # may be any number of characters indicating non-safety related model differences)
Rating:	Input: 100-240 Vac; 47-63 Hz; 2.2 A max. Output: Forced air cooling ZMS100-12 12Vac; 8.4A; 100,8W ZMS100-15 15Vac 6.7A; 100,5W ZMS100-24 24Vac; 4.2A; 100,8W ZMS100-28 28Vac; 3.6A; 100,8W ZMS100-36 36Vac; 2.8A; 100,8W ZMS100-48 48Vac; 2.1A; 100,8W Convection cooling ZMS100-12 12Vac; 6.7A; 80,4 W ZMS100-15 15Vac; 5.4A; 81W ZMS100-24 24Vac; 3.4A; 81,6W ZMS100-28 28Vac; 2.9A; 81,2W ZMS100-36 36Vac; 2.25A; 81W ZMS100-48 48Vac; 1.67A; 80,2W
Applicant Name and Address:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE EX34 8ES UNITED KINGDOM

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: Ermanno Rebbechi

Reviewed by: Dennis Butcher

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 power supply is an open frame switch mode power supply for building-in.
The power supply can be used as Class I or Class II construction.

Model Differences

All models use different transformer constructions. The secondary output windings have a different number of turns to get different secondary output voltages.

12V and 15V models have an additional secondary winding (W4). This winding is not used for the other models. Winding W4 utilises triple insulated wire, which provides reinforced insulation between the output contacts. Therefore, no short or overload was applied directly on the output contacts.

2 different PCB layouts are used: the 12V & 15V models have the same PCB layout, and the 24V, 28V, 36V and 48V models have the same PCB layouts.

Technical Considerations

- Classification of installation and use : Fixed: for building-in
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : None
- Mode of operation : Continuous
- Supply connection : not directly connected to the mains. End product consideration
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: 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)
- 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 following accessories were investigated for use with the product:: none
- 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:

- Considerations to the applied parts requirement, to be conducted as end-product
- Attention to the temperature limit of 50°C shall be considered in the end-use application when determining the appropriate level of airflow across the unit.
- 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 input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.
- The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
- This power supply provides the following MOPP (means of patient protection)/MOOP (means of operator protection): , Between Primary and Earth (all models): 1MOPP/1 MOOP based upon a working voltage 240 Vrms, 340 Vpk , -- , Between Primary to Secondary (ZSM100-12 & ZSM100-15): 2MOPP based upon a working voltage 256 Vrms, 576 Vpk , Between Secondary and Earth (ZSM100-12 & ZSM100-15): 1MOPP based upon a working voltage 240 Vrms, 340 Vpk , -- , Between Primary to Secondary (ZSM100-24, ZSM100-28, ZSM100-36, ZSM100-48): 2MOPP based upon a working voltage 273 Vrms, 586 Vpk , Between Secondary and Earth (ZSM100-24, ZSM100-28, ZSM100-36, ZSM100-48): 1MOPP based upon a working voltage 240 Vrms, 340 Vpk
- 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.
- Proper bonding to the end-product main protective earthing termination is required for all Class I models only.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C at Full Load.
- Magnetic device TX1 employs a Class F (155°C) or higher insulation system.
- The PWB is rated 130°C
- 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 end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- For Power Supplies with No RM: , • 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. , • End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply. , • End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply. , • End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply , • End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply

Additional Information

The following components are glued to prevent movement:

- For 12V & 15V models: RT1, C5, C11, C7, C8, C9, C12, FE wire on PCB near C8, primary windings of transformer TX1 on PCB
- 24V, 28V, 36V and 48V models: RT1, C5, C6, C7, C8, C11, C2, FE wire on PCB near C2/C11, primary windings of transformer TX1 on PCB

The power supply can be used as Class I or Class II construction.

- For Class I construction, the SMPS must be reliably earthed and professionally installed and fixed with metal screws.
- For Class II construction no earthing connection is required. The SMPS must be fixed so that it is insulated

from any unearthed accessible conductive part by at least 1 x MOPP for a working voltage of 240 Vrms (e.g. fixed to metal enclosure by means of plastic spacers and plastic screws).

The power supply provides two supplementary fuses, one in Line and one in Neutral.

The power supply may be either forced air or convection cooled. Due to the fact that air flow for cooling depends on end product use, only convection cooling was considered during temperature measurement.

Therefore, the following temperatures within end equipment use shall not be exceeded:

Therefore, the following temperatures within end equipment use shall not be exceeded:


Circuit Ref.	Description	Max. Temperature (°C)
L1	Common Mode Choke	155
C6, C7, C8	Electrolytic Capacitors	105
C5	Electrolytic Capacitors	105
C1	X Capacitor	100
C2, C3, C4, C10, C11	Y Capacitors	125
TX1	Transformer Winding	140
XU2, XU4	Opto-Coupler	100
J1	Input Connector	85
J2	Output Connector	85

Additional Standards

The product fulfills the requirements of: CSA CAN/CSA-C22.2 NO. 60601-1:14

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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
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.

Special Instructions to UL Representative

7.2.6 Class II Equipment: only on models designated as Class II

Production-Line Testing Requirements			
Test Exemptions - The following models are exempt from the indicated test			
Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
Class II models	exempt	required	exempt
Class I models	required	required	exempt
Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:			
Component			
N/A			
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	none	none	none

TABLE: List of Critical Components

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
PVB's					
J1 Input Connector	Interchangeable Molex Inc.	Interchangeable 10-63-4027 (5096 series)	94V-1 (Minimum) 130°C UL: 250V, 7A, 105°C	ZPMV2 ECBT2: E29179	UR UR
J1 Input Connector (alternative)	Amtek Technology Co. Ltd	3961SA-03TW-M01-L	UL: 250V, 7A, 85°C	ECBT2: E322618	UR
J1 Input Connector (alternative)	JST	VH Series	UL: 250V, 7A, 85°C	ECBT2: E60389	UR
J1 Input Connector (alternative)	Interchangeable	Interchangeable	UL: 250V min, 7A min, 85°C min.	ECBT2	UR
J2 Output Connector	JST	VH Series	UL: 250V, 10A, 85°C	ECBT2: E60389	UR
J2 Output Connector (alternative)	Alex Connector Co. Ltd	8673-N Series	UL: 250V, 7A, 105°C	ECBT2: E114003	UR
J2 Output Connector (alternative)	Molex UK	5273 Series	UL: 250V, 7A, 105°C	ECBT2: E29179	UR
J2 Output Connector (alternative)	Interchangeable	Interchangeable	UL: 250V min, 10A min, 85°C min	ECBT2	UR
J3 Earth Tab	Interchangeable	Interchangeable	Plated copper or copper alloy, 6.35 x 15.8mm x 0.8mm	-	-
XR1, XR2, Discharge resistors	Interchangeable	Interchangeable	390K ohm max, 0.25W min	-	-
F1 & F2 fuse	Belfuse	RST Series	T3.15AL, 250V, 8.35x7.2x4mm	JDYX2: E20624	UR
F1 & F2 fuse (alternative)	Littelfuse	392 Series	T3.15AL, 250V, 8.5x7.4x4mm	JDYX2: E67006	UR
RT1 Thermistor	Joyin Co Ltd	JNR Series 10S100L	125°C Required for safety (eng. Note: cURus component with EN/IEC60738-1 Annex J)	XGPU2: E171531	UR
C1 X capacitor	Carli Electronics Co. Ltd.	MPX series	680nF max, 275Vac, X2, 100°C	FOWX2: E120045	UR
C1 X capacitor (alternative)	Vishay Capacitors Belgium N V	MKP338-2 series	680nF max., 310 Vac, X2, 105°C	FOWX2: E354331	UR
C1 X capacitor	Kemet Electronics	PHE840M series	680nF max., 275 Vac, X2, 105°C	FOWX2: E73869	UR

Object/part or Description (alternative)	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
C1 X capacitor (alternative)	OY				
C1 X capacitor (alternative)	Kemet Electronics Italia SRL	R.46 Series	680nF max., 275 Vac, X2, 110°C	FOWX2. E97797	UR
C1 X capacitor (alternative)	Vishay Capacitors Belgium, N.V	MKP336-2 series	680nF max., 250 Vac, X2, 105°C	FOWX2. E354331	UR
C1 X capacitor (alternative)	Okaya Electric Industries Co. Ltd.	LE-MX Series	680nF max., 250 Vac, X2, 110°C	FOWX2. E47474	UR
C1 X capacitor (alternative)	Xiamen Faratronic Co.Ltd.	MKP62 series	680nF max., 275 Vac, X2, 110°C	FOWX2. E186600	UR
L1 Common mode choke	TDK lambda or Trio Engineering Co Ltd	TDKL Part No: 33417	Core: OD 20mm ID 16mm, depth 12mm. Wire: Class F 0.5mm min. ECW Bobbin:- Manufactured by El Dupont Rynite FR530 or FR530L, 0.7mm thick min rated 94V-0, RTI 155°C.	-	-
C2, C3, C4, C10, C2, C11 Y Capacitor	Murata	KX Series	1nF max, 250Vac, Y1, 125°C	FOWX2. E37921	UR
C2, C3, C4, C10, C2, C11 Y Capacitor (alternative)	Kemet Electronics OY	ERP Series	1nF max, 250Vac, Y1, 125°C	FOWX2. E356389	UR
ASY1-A	+ Rectron	RBU607M	700 V; 6 A	QQQX2. E252754	UR
Diode bridge	Interchangeable	Interchangeable		-	-
C5 Reservoir Capacitor	Interchangeable	Interchangeable	220uF max, 400Vac min, 105°C	QMFZ2. E121562	UR
Insulator for Capacitor C5	Interchangeable	Lexan FR700	0.25mm thick min, 50.5 x 10mm		
Insulator for Capacitor C5 (alternative)	Interchangeable	Nomex type 410	0.125mm thick min, 50.5 x 10mm	QMFZ2. E34739	UR
Sleeving for leg of C5 capacitor	TE Connectivity	Versafit-3/64-0-SP-SM	ID 1.63mm thick min, VW-1	YDPU2. E35586	UR
Sleeving for leg of C5 capacitor (alternative)	Interchangeable	Interchangeable	ID 1.63mm thick min, VW-1	YDPU2	UR
TX1 Transformer (12V, 15V)	TDK-Lambda UK Ltd or Trio Engineering Co Ltd	TDKL Part No: 230040 No.: 230066	Class F Reinforced insulation, systems CEL-CF4 or TEC-CF4	OBJY2	UL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
TX1 Transformer (24V, 28V, 36V, 48V)	TDK-Lambda UK Ltd or Trio Engineering Co Ltd	TDKL Part No: 230057 No: 230082 No: 230058 No: 230059	Class F Reinforced insulation, systems CEL-CF4 or TEC-CF4	OBJY2	UL
TX1 Transformer core	Interchangeable	Interchangeable	2 PQ-cores total 27mm x 25mm x 19mm	-	-
TX1 Transformer bobbin	Sumitomo Bakelite Co Ltd	PM-9820	Rated V-0; 150°C at 0,16 mm thickness	QMFZ2. E41429	UR
TX1 Transformer bobbin	Interchangeable	Interchangeable	According to UL insulation system	QMFZ2	UR
TX1 Transformer (12V, 15V) triple insulated wire	New England	W221T1.5E***** and W281T1.5E***** (ETFE)	Triple insulated wire; rated 155°C Diameter: W1, W5: 22AWGW2, W4: 28AWG	OBJT2. E205791	UR
TX1 Transformer (24V,28V, 36V, 48V) triple insulated wire	New England	W221T1.5E***** and W281T1.5E***** (ETFE)	Triple insulated wire; rated 155°C Diameter: W1, W5: 22AWGW2, W4: 28AWG	OBJT2. E205791	UR
Optocoupler XU2 (Only 24V, 28V, 36V, 48V units) XU3 (Only 12V, 15V units) XU4 (all units)	Vishay	SFH6156-3	Provides reinforced insulation. Distance through insulation 0.4mm min: 4420Vac	FPQU2. E52744	UR
Wire between CCT Ref H2 and H3	New England	Triple Insulated Wire	26 AWG (0.4mm) minimum, Provides reinforced insulation	OBJT2. E205791	UR
Wire between CCT Ref H2 and H3 (alternative)	Furukawa	TEX-E	26 AWG (0.4mm) minimum, Provides reinforced insulation.	OBJT2. E206440	UR
Sleeving over wire between CCT Ref H2 and H3	Vitar Insulation Manufacturers Ltd	GS-1U	200°C, 600V, VW-1, 0.5mm thick min.	UZFT2. E166149	UR
Sleeving over wire between CCT Ref H2	Shenzhen Wahchangwei	SRS-70	200°C, 600V, VW-1, 0.5mm thick min.	UZFT2. E233803	UR

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
and H3 (alternative) Sleeving over wire between CCT Ref H2 and H3 (alternative)	Industrial Co Ltd Interchangeable	Interchangeable	200°C, 600V, VW-1 (min), 0.5mm thick min.	UZFT2	UR
Optional coating, may be used on all parts of PSU	Dymax Corporation	984-LVUF	120°C	QMJU2. E140512	UR
Optional coating, may be used on all parts of PSU (alternate)	Dow Corning	1-2577 or 1-2577 Low VOC	130°C	QMJU2. E81611	UR
Optional coating, may be used on all parts of PSU (alternate)	Lackwerke Peters GmbH & Co KG	DSL 1600E-FLZ	125°C	QMJU2. E80315	UR

Enclosures

<u>Type</u>	<u>Supplement Id</u>	<u>Description</u>
Photographs	3-01	ZMS100-12
Photographs	3-02	ZMS100-15
Photographs	3-03	ZMS100-24
Photographs	3-04	ZMS100-28
Photographs	3-05	ZMS100-36
Photographs	3-06	ZMS100-48
Miscellaneous	7-01	Marking plates