

COPY

US-TUVR-4428

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

Product Produit

Name and address of the applicant Nom et adresse du demandeur

Name and address of the manufacturer Nom et adresse du fabricant

Name and address of the factory Nom et adresse de l'usine

Note: When more than one factory, please report on page 2 Note: Lorsque il y plus d'une usine, veuillez utiliser la 2^{ene} page

Ratings and principal characteristics Valeurs nominales et caractéristiques principales

Trademark (if any) Marque de fabrique (si elle existe)

Model / Type Ref. Ref. De type

Additional information (if necessary, may also be reported on page 2)

Les informations complémentaires (si nécessaire, peuvent être indiqués sur la 2^{éme} page)

A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la

As shown in the Test Report Ref. No. which forms part of this Certificate

Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat

Medical Power Supply

SL Power Electronics Corp. 7105 Northland Terrace Minneapolis, MN 55428 US

same as applicant

SL Power Electronics Xianghe Anping Economic and Technical Developing Zone Xianghe County, Hebei 065402 China

Additional Information, see page 2

SL POWER ELECTRONICS, AULT

Additional Information, see page 2

Complies with requirements as well as group and national differences where applicable for: AU, CA, DK, IL, KR, and US. (SMT)

PUBLICATION

EDITION

IEC 60601-1+Amd1+Amd2

2nd Edition (1988)

30881140.001

This CB Test Certificate is issued by the National Certification Body Ce Certificat d'essai OC est établi par l'Organisme National de Certification



TÜVRheinland®

Precisely Right. July 10, 2008

Page 1 of 2

Signature:

Marlies Raap



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Additional Information:

I. Model / Type Ref.:

MW155

The model designation has the following suffix: X1X2X3X3X4X4X5X6X6.

The suffix describes the features of the power supply as follows:

X1 = A - Z; designates manufacturing location

X2 = A - Z; indicates design revision that represent non-safety related features

X3X3 = 12, 15, 18 or 24; represents output voltage

X4, X6 = 0-9; represent non-safety relevant features such as different configuration of the SELV connector, variations or additional marking, etc.

X5 = F; indicates type of appliance inlet

II. Ratings and principal characteristics:

Input: 1) AC 100-110V, 50-60Hz, 2.0A or

AC 110-240V, 50-60Hz, 2.0-1.0A; (X3X3=12)

2) AC 100-240V, 50-60Hz, 2.0-1.0 A; (X3X3=15, 18, 24)

Output: 1) DC + 12V, 8.33A or DC +12V, 9.165A; (X3X3=12)

2) DC + 15V, 7.33A; (X3X3=15) DC + 18V, 6.66A; (X3X3=18) DC + 24V, 5.0A; (X3X3=24)

Protection Class: I

This CB Test Certificate is issued by the National Certification body Ce Certificat d'essai OC est établi par l'Organisme National de Certification



July 10, 2008

Page 2 of 2

Signature:



Date:

Report Reference # Issue Date: 2008-05-16 Page 1 of 2 E145177-A9-UL-1

Correction 1 2009-04-10

COVER PAGE FOR TEST REPORT

Product Category: Power Supplies, Medical and Dental

Product Category CCN: QQHM2, QQHM8

Test Procedure: Component Recognition Product: Component Power Supply

Model/Type Reference: MW155RAXYFZ, where X represents the output voltage which may be the

> number 12, 15, 18 or 24; Y indicates the output connector style which may be any number from 00-99; F indicates the C14 type AC inlet; and Z represents non-safety related customer options which may be any number from 00-99.

Rating(s): Input: 100-240 V~, 50-60 Hz, 2.0-1.0 A

Output:

MW155RA12YFZ: 12 V dc/8.33 (100-110 V~); 12 V dc/9.165 A (>110-240 V~)

MW155RA15YFZ: 15 V dc/7.33 A MW155RA18YFZ: 18 V dc/6.66 A MW155RA24YFZ: 24 V dc/5.0 A

Standards: UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1:

General Requirements for Safety)

CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1:

General Requirements for Safety)

Applicant Name and

SL POWER ELECTRONICS CORP

Address: 6050 KING ST

> VENTURA CA 93003 **UNITED STATES**

This Report includes the following parts, in addition to this cover page:

1. Specific Technical Criteria

2. Clause Verdicts

Issue Date: 2008-05-16 Page 2 of 2 Report Reference # E145177-A9-UL-1

Correction 1 2009-04-10

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 Underwriters Laboratories Inc. ('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 Underwriters Laboratories Inc. (UL) or any authorized licensee of UL.

Test Report By:

Ahmad Daoudi

Engineering Associate

Underwriters Laboratories Inc.

Reviewed By:

Marc M. Mouser

Manager

Underwriters Laboratories Inc.

Issue Date: 2008-05-16 Page 1 of 5 Report Reference # E145177-A9-UL-1

Correction 1 2009-04-10

SPECIFIC TECHNICAL CRITERIA

TEST REPORT UL 60601-1

Medical Electrical Equipment

Part 1: General requirements for safety

Report Reference No E145177-A9-UL-1
Compiled by Ahmad Daoudi

Reviewed by Marc M. Mouser

Date of issue 2008-05-16

Part 1: General Requirements for Safety)

CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment -

Part 1: General Requirements for Safety)

Test procedure Component Recognition

Non-standard test method: N/A

Test item description Component Power Supply

Trademark:

SIL

Model and/or type reference: MW155RAXYFZ, where X represents the output voltage which may be

the number 12, 15, 18 or 24; Y indicates the output connector style which may be any number from 00-99; F indicates the C14 type AC inlet; and Z represents non-safety related customer options which may

be any number from 00-99.

Rating(s) Input: 100-240 V~, 50-60 Hz, 2.0-1.0 A

Output:

MW155RA12YFZ: 12 V dc/8.33 (100-110 V~); 12 V dc/9.165 A

(>110-240 V~)

MW155RA15ÝFZ: 15 V dc/7.33 A MW155RA18ÝFZ: 18 V dc/6.66 A MW155RA24ÝFZ: 24 V dc/5.0 A Issue Date: 2008-05-16 Page 2 of 5 Report Reference # E145177-A9-UL-1

Correction 1 2009-04-10

GENERAL INFORMATION				
Test item particulars (see also clause 5):				
Classification of installation and use	.:	Portable		
Supply connection	.:	Appliance coupler		
Accessories and detachable parts included in the evaluation	:	None		
Options included	.:	None		
Possible test case verdicts:				
- test case does not apply to the test object	.:	N / A		
- test object does meet the requirement	.:	P(Pass)		
- test object does not meet the requirement	.:	F(Fail) (acceptable only if a corresponstringent national requirement is "Pas		
Abbreviations used in the report:				
- normal condition:	N.C.	- single fault condition:	S.F.C.	
- operational insulation:	OP	- basic insulation:	BI	
- basic insulation between parts of opposite polarity:	BOP	- supplementary insulation:	SI	
- double insulation:	DI	- reinforced insulation:	RI	
General remarks:				
- "(see Enclosure #)" refers to additional information appended to the Test Report				
- "(see appended table)" refers to a table appended to the Test Report				
- Throughout the Test Report a point is used as the decimal separator				

General	Product Information:			
CA1.0	Report Summary			
CA1.1	N/A			
CB1.0	Product Description			
CB1.1	The MW155RAXYFZ is used as a desktop and/or portable power supply. A green LED is provided to indicate DC output is present.			
CC1.0	Model Differences			
CC1.1	The MW155RAXYFZ is Class I unit, where X represents the output voltage which may be the number 12, 15, 18 or 24; Y indicates the output connector style which may be any number from 00-99; F indicates the C14 type AC inlet; and Z represents non-safety related customer options which may be any number from 00-99. The transformers have different turns and gage but have similar construction.			

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Correction 1 2009-04-10

Issue Date:

CD1.0	Additional Information		
CD1.1	The schematics are kept on file at the CB Testing Laboratory mentioned in the first page of this test report, and can be provided by the applicant upon request by CBTLs/NCBs. All tests were conducted at the SMT facility.		
CE1.0	Technical Considerations		
CE1.1	The product was investigated to the following additional standards:	UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada), UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA)	
CE1.2	The product was not investigated to the following standards or clauses:	Clause 36, Electromagnetic Compatibility (IEC 601-1-2), Clause 48, Biocompatibility (ISO 10993-1), Clause 52.1, Programmable Electronic Systems (IEC 601-1-4),	
CE1.3	The product is Classified only to the following hazards:	Casualty, Fire , Shock	
CE1.4	The degree of protection against harmful ingress of water is:	Ordinary	
CE1.5	The following accessories were investigated for use with the product:	,	
CE1.6	The mode of operation is:	Continuous	
CE1.7	Software is relied upon for meeting safety requirements related to mechanical, fire and shock:	No	
CE1.8	The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:	No	
CF1.0	Engineering Conditions of Acceptability		
CF1.1	For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc.		
	When installed in an end-product, consideration must be given to the following:		
CF2.0	This component has been judged on the basis of the required spacings in the First Edition of the Standards for Medical Electrical Equipment, Part 1: General Requirements for Safety, UL 60601-1, which covers the end use product for which the component is designed.		
CF2.1	The component is provided with a plastic enclosure and an appliance inlet		

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Correction 1 2009-04-10

	The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).	
	The Temperature Test was performed in an ambient of 25 °C and were calculated for a raised ambient of 40 °C. In some instances, the temperature test was repeated in an ambient of 40 °C to validate the calculation.	
	The power supply was evaluated as Reinforced insulation between primary and secondary; basic insulation between primary to heatsink; and operational insulation between secondary to heatsink.	
	This power supply has been evaluated as Class I equipment, continuous operation, and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.	
	The output has been evaluated and tested for operator accessible part. Under normal and single fault conditions, the outputs do not exceed 25 V ac or 60 V dc.	
	The product was evaluated for desktop and/or portable use only. Additional evaluation may be required as part of end product investigation to insure compliance of the product as mobile device.	
	Leakage current measurements must be performed on the combination power supply and the end-use product.	
	Installation instructions and end product markings are the responsibility of the end-use product manufacturer.	
	At 90V~ input, the 12V model output is derated to 12Vdc, 8.33A to comply with the temperature limit. Above 90V~ input, the 12V model complies with the temperature limit with a rated output 12Vdc, 9.165A	
	Earth leakage current was measured using Figs 10 and 11 of UL60601-1.	
DF2.7 DF2.8 DF2.9 DF3.1	operator accessible part. Under normal and single fault conditions, the outputs do not exceed 25 V ac or 60 V dc. The product was evaluated for desktop and/or portable use only. Additional evaluation may be required as part of end product investigation to insure compliance of the product as mobile device. Leakage current measurements must be performed on the combination power supply and the end-use product. Installation instructions and end product markings are the responsibility of the end-use product manufacturer. At 90V~ input, the 12V model output is derated to 12Vdc, 8.33A to comply with the temperature limit. Above 90V~ input, the 12V model complies with the temperature limit with a rated output 12Vdc, 9.165A Earth leakage current was measured using Figs	



Certificate

Certificate no.

T 72061595 41

License Holder:

SL Power Electronics Corp. 7105 Northland Terrace Minneapolis MN 55428 USA

Manufacturing Plant:

SL Power Electronics Xianghe Anping Economic and Technical Developing Zone

065402 Xianghe County, Hebei China

Test report no.: USA-JAK 09571156 062

Client Reference: Tim Cassidy

Tested to:

EN 60601-1:1990+A1+A2+A13

Certified Product: Medical Power Supply

License Fee - Units

Addition:

Model Designation: MW155X1X2X3X3X4X4X5X6X6

(X1, X2 = A-Z; X4, X6 = 0-9; X5 = F;X1, X2, X4, X6 not safety-relevant)

Rated Voltage:

1) AC 100-110V, 50-60Hz;

or AC 110-240V, 50-60Hz; (X3X3=12) 2) AC 100-240V, 50-60Hz; (X3X3=15,18,24)

Rated Current:

1) 2.0A or 2.0-1.0A;

Protection Class:

2) 2.0-1.0A

contd.

Appendix: 1, 1-5

Inh. = 747695 / Deb. = 747695 / Fert. = 751962

Licensed Test mark:

EN 60601-1

Signatures

Date of Issue (day/mo/yr) 08/07/2008

President

QA Certification Officer

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 96470, Tel (203) 426 9888 Fax (203) 426 4009



Certificate

Certificate no.

T 72061595 42

License Holder:

SL Power Electronics Corp. 7105 Northland Terrace Minneapolis MN 55428 USA

Manufacturing Plant:

SL Power Electronics Xianghe Anping Economic and Technical Developing Zone

065402 Xianghe County, Hebei China

Test report no.: USA-JAK 09571156 062 Client Reference: Tim Cassidy

Tested to: EN 60601-1:1990+A1+A2+A13

Certified Product: Medical Power Supply

License Fee - Units

contd.

Output Ratings: 1) DC +12V, 8.33A (X3X3=12)

DC +12V, 9.165A (X3X3=12)

(X3X3=15)

2) DC +15V, 7.33A DC +18V, 6.66A (X3X3=18)

DC +24V, 5.0A (X3X3=24)

Inh. = 747695 / Deb. = 747695 / Fert. = 751962

Licensed Test mark:

EN 60601-1

Signatures

Date of Issue (day/mo/yr) 08/07/2008

President

QA Certification Officer

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, Tel (203) 426 0888 Fax (203) 426 4009