

IEC SYSTEM FOR CONFORMITY TESTING AND
CERTIFICATION OF ELECTRICAL EQUIPMENT (IECEE)
CB SCHEME

SYSTEME CEI D'ESSAIS DE CONFORMITE ET DE CERTIFICATION
DES EQUIPEMENTS ELECTRIQUES (IECEE)
METHODE OC

CB TEST CERTIFICATE CERTIFICAT D'ESSAI OC

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

Rating 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)
Information complémentaire (si nécessaire)

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

Power Supply

SL Power Electronics Corp
6050 King St
Ventura, CA 93003, USA

SL Power Electronics Corp
6050 King St
Ventura, CA 93003, USA

1. Industrias S L S A De C V
Costa Rica #60, Col Cuahutemoc
Mexicali, Baja, California N, Mexico
2. SL Power Electronics Xianghe
Anping Economic & Tech Developing Zone
Xianghe, Hebei 065402, China

GEM600-VV-WXY-ZZ G, Input: 100-240 V~, 50/60 Hz, 9 A/4.5 A
GEM750-VV-WXY-ZZ G, Input: 100-240 V~, 50/60 Hz, 11 A/5.5 A
(For Output Information see Test Report).



GEM600-VV-WXY-ZZ G and GEM750-VV-WXY-ZZ G. Where VV is the output Voltage 24-48VDC, may also be followed by "-XYZ", where W is an Alpha character A or T, which represents the Input Connector, X is an alpha character A, B or T which represents the Output Connector, Y is an Alpha Character D, which represents the Optional OR-ing Diode, may also be followed by "-ZZ" is any numeric character 00-99 which represents Value Added Configurations not related to safety and "G" indicates compliance with the RoHS directive. (RoHS compliance has not been evaluated by UL.)

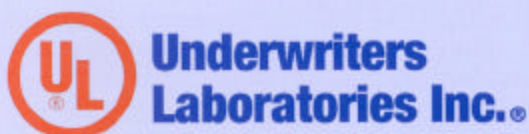
The CB Test Report comprises 6 enclosures.

PUBLICATION EDITION

**IEC 60601-1 (1988) Second Edition,
with Amendment No. 1 (1991) and No. 2 (1995)** with the exception of:
Clause 36, Electromagnetic Compatibility, Clause 48, Biocompatibility and Clause 52.1,
Programmable Electronic Systems. Inclusive of CENELEC Common Modifications.
See Test Report for National Differences.

E116994-A37-CB-1

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

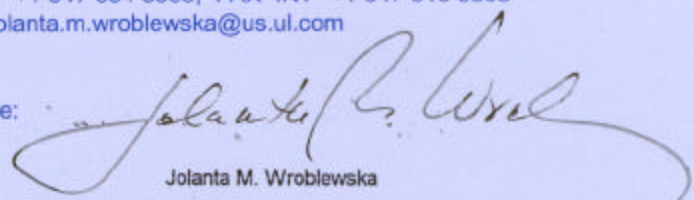


Underwriters Laboratories Inc. / Certification Programs Office, USA
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email: jolanta.m.wroblewska@us.ul.com

Date:

Issued: 2007 September 24

Signature:




Jolanta M. Wroblewska

COVER PAGE FOR TEST REPORT

Test Item Description:	Power Supply																						
Model/Type Reference:	GEM600-VV-WXY-ZZ G and GEM750-VV-WXY-ZZ G. Where VV is the output Voltage 24-48VDC, may also be followed by "-XYZ", where W is an Alpha character A or T, which represents the Input Connector, X is an alpha character A, B or T which represents the Output Connector, Y is an Alpha Character D, which represents the Optional OR-ing Diode, may also be followed by "-ZZ" is any numeric character 00-99 which represents Value Added Configurations not related to safety and "G" indicates compliance with the RoHS directive. (RoHS compliance has not been evaluated by UL.)																						
Rating(s):	<p>GEM600-VV-WXY-ZZ G Input: 100-240 V~, 50/60 Hz, 9 A/4.5 A</p> <p>GEM750-VV-WXY-ZZ G Input: 100-240 V~, 50/60 Hz, 11 A/5.5 A</p> <p>Output:</p> <p>GEM600</p> <table><thead><tr><th>V</th><th>A</th></tr></thead><tbody><tr><td>24</td><td>25</td></tr><tr><td>28</td><td>21.5</td></tr><tr><td>36</td><td>16.7</td></tr><tr><td>48</td><td>12.5</td></tr></tbody></table> <p>GEM750</p> <table><thead><tr><th>V</th><th>A</th></tr></thead><tbody><tr><td>24</td><td>31.2</td></tr><tr><td>28</td><td>26.8</td></tr><tr><td>32</td><td>23.4</td></tr><tr><td>36</td><td>20.8</td></tr><tr><td>48</td><td>15.6</td></tr></tbody></table> <p>+ Maximum current output with Airflow of 42 CFM with an integral fan at an ambient of 50°C.</p>	V	A	24	25	28	21.5	36	16.7	48	12.5	V	A	24	31.2	28	26.8	32	23.4	36	20.8	48	15.6
V	A																						
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28	26.8																						
32	23.4																						
36	20.8																						
48	15.6																						
Standards:	IEC 60601-1:1988 + A1:1991 + A2:1995																						
Applicant Name and Address:	SL POWER ELECTRONICS CORP 6050 KING ST VENTURA CA 93003																						
Factory Location(s):	INDUSTRIAS S L S A DE C V COSTA RICA #60 COL CUAHUTEMOC MEXICALI BAJA CALIFORNIA N MEXICO																						
	SL POWER ELECTRONICS XIANGHE ANPING ECONOMIC & TECH DEVELOPING ZONE XIANGHE,																						

Demko Certificate

Product: Power Supply
Manufacturer: SL POWER ELECTRONICS CORP
6050 KING ST
VENTURA CA 93003
Production site: See appendix
Certified by request of: SL POWER ELECTRONICS CORP
6050 KING ST
VENTURA CA 93003
Trademark: 
Model/Type ref.: See appendix
Rated current or power: See appendix
Rated voltage: See appendix
Insulation Class: I
Degree of protection: -
Additional information: See appendix

Variants covered by this certificate are specified in the attached appendix.
Detailed specification of the certified product(s) is listed in the appendix.

A sample of the product has been tested and found in conformity with EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996 , as shown in the Test Report from Underwriters Laboratories Inc. with ref. No. E116994-A37-CB-1

Furthermore, the product complies with the national deviations in Denmark.

Date of expiry: 2009-09-12

UL International Demko AIS is a body notified to the Member States and Commission of the European Communities according to the provisions of Article 8 of the Low Voltage Directive.

The Manufacturer complies with the Production Surveillance Requirements. Products included in this certificate are allowed to carry the registered approval marks of UL International Demko AIS, or for cables <DEMKO>. The name of UL International Demko AIS can be used in the marketing of the products. This Statement is only valid for products, which are identical to the tested product, and manufactured at the above-mentioned production site(s). UL International Demko AIS has to be informed in writing about any changes, in accordance with the " UL International Demko AIS Standard Terms and Conditions" for UL International Demko AIS services. The validity of this certificate is shortened if the EU legislation requires re-testing and re-certification, due to new standards or amendments coming into force, before the expiry date.

Herlev, 2007-10-08


Jan-Erik Storgaard
Certification Manager

UL International Demko A/S

Lyskaer 8, P.O. Box 514
DK-2730 Herlev, Denmark
Telephone: +45 44856565
Fax: +45 44856500



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**Underwriters
Laboratories Inc.®**

Appendix to Demko Certificate No. 143848-01

The Certificate covers the following:

01; GEM600-VV-WXY-ZZ G; 100-240 Vac, 50/60Hz; 9A/4.5A

Output: 24 Vdc, 25.0 A
28 Vdc, 21.5 A
36 Vdc, 16.7 A
48 Vdc, 12.5 A

02; GEM750-VV-WXY-ZZ G; 100-240 Vac, 50/60 Hz; 11 A/5.5 A

Output: 24 Vdc, 31.2 A
28 Vdc, 26.8 A
32 Vdc, 23.4 A
36 Vdc, 20.8 A
48 Vdc, 15.6 A

For building-in

Where VV is the output

Voltage 24-48VDC, may also be followed by "-XYZ", where W is an Alpha character A or T, which represents the Input Connector, X is an alpha character A, B or T which represents the Output Connector, Y is an Alpha Character D, which represents the Optional OR-ing Diode, may also be followed by "-ZZ" is any numeric character 00-99 which represents Value Added Configurations not related to safety and "G" indicates compliance with the RoHS directive.

Production Site:

INDUSTRIAS S L S A DE C V
COSTA RICA #60
COL CUAHUTEMOC
MEXICALI
BAJA CALIFORNIA N MEXICO

SL POWER ELECTRONICS XIANGHE
ANPING ECONOMIC & TECH DEVELOPING ZONE
XIANGHE, HEBEI 065402 CHINA

The certificate has been issued on the basis of CB certificate (CB Test certificate) No. US/11940/UL, issued by Underwriters Laboratories Inc., dated 2007-09-24

Herlev, 2007-10-08


Jan-Erik Storgaard
Certification Manager


UL International Demko A/S

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SPECIFIC TECHNICAL CRITERIA

<p>TEST REPORT UL 60601-1 Medical Electrical Equipment Part 1: General requirements for safety</p>											
Report Reference No	E116994-A37-UL-1										
Compiled by	Ahmad Daoudi										
Reviewed by	Kent C. Jones										
Date of issue	2007-09-21										
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)										
Test procedure	Component Recognition										
Non-standard test method	N/A										
Test item description	Power Supply										
Trademark											
Model and/or type reference	GEM600-VV-WXY-ZZ G and GEM750-VV-WXY-ZZ G. Where VV is the output Voltage 24-48VDC, may also be followed by "-XYZ", where W is an Alpha character A or T, which represents the Input Connector, X is an alpha character A, B or T which represents the Output Connector, Y is an Alpha Character D, which represents the Optional OR-ing Diode, may also be followed by "-ZZ" is any numeric character 00-99 which represents Value Added Configurations not related to safety and "G" indicates compliance with the RoHS directive. (RoHS compliance has not been evaluated by UL.)										
Rating(s)	GEM600-VV-WXY-ZZ G Input: 100-240 V~, 50/60 Hz, 9 A/4.5 A GEM750-VV-WXY-ZZ G Input: 100-240 V~, 50/60 Hz, 11 A/5.5 A Output: GEM600 <table style="margin-left: 20px;"> <tr><td>V</td><td>A</td></tr> <tr><td>24</td><td>25</td></tr> <tr><td>28</td><td>21.5</td></tr> <tr><td>36</td><td>16.7</td></tr> <tr><td>48</td><td>12.5</td></tr> </table> GEM750	V	A	24	25	28	21.5	36	16.7	48	12.5
V	A										
24	25										
28	21.5										
36	16.7										
48	12.5										

V	A
24	31.2
28	26.8
32	23.4
36	20.8
48	15.6

+ Maximum current output with Airflow of 42 CFM with an integral fan at an ambient of 50°C.

GENERAL INFORMATION			
Test item particulars (see also clause 5):			
Classification of installation and use	:	For building-in	
Supply connection	:	Terminal block	
Accessories and detachable parts included in the evaluation	:	None	
Options included	:	Terminal Block, Bussbars, Phoenix Contact, or N+1 OR-ing Diode.	
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 corresponding, less stringent national requirement is "Pass")	
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 equipment (DC power supplies) covered by this report are components which are intended for use in end-product equipment used in a hospital or related health care facility, evaluated to the standard for Medical Equipment. The GEM Series or power supplies are designed for building-in to an end product. They are designed with 1 cover mounted integral fan rated at 42 CFM. Rated Ambient is 50°C.
CC1.0	Model Differences
CC1.1	All models within the Model Series GEM600 are similar to each other except for Main Power

	<p>Transformers and minor component changes.</p> <p>All models within the Model Series GEM750 are similar to each other except for the Main Power Transformers and minor component changes.</p> <p>Model Series GEM600 and Model Series GEM750 are similar, except for the Power FET's, which are more robust in the GEM750 Series.</p> <p>Nomenclature for Model Series GEM600-VV-WXY-ZZ G and Model Series GEM750-VV-WXY-ZZ G, where</p> <p>VV = the output Voltage 24-48VDC W = an Alpha character A or T, which represents the Input Connector, X = an alpha character A, B or T which represents the Output Connector, Y = an Alpha Character D, which represents the Optional OR-ing Diode, -ZZ= any numeric character 00-99 which represents Value Added Configurations not related to safety G = indicates compliance with the RoHS directive. (RoHS compliance has not been evaluated by UL.)</p> <p>OPTIONS: A - Terminal Block (EBY P/N 5002-03-N-12) B - Bussbars T - Phoenix Contact (P/N 173204) D - N+1 OR-ing Diode. Will allow 2 or more power supplies to be connected in parallel and share the output load.</p>	
CD1.0	Additional Information	
CD1.1	<p>The schematics for these models 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 CBTL's/NCB's.</p> <p>Only limited testing was considered necessary on Model GEM750-48 due to testing conducted as part of a similar already evaluated Model Series GPHP600 and GPHP750 covered under Test Report Reference E116994-A16-CB-1, CB Certificate US/8708/UL .</p>	
CE1.0	Technical Considerations	
CE1.1	<p>The product was investigated to the following additional standards:</p>	<p>EN 60601-1: 1990 + A1:1993 + A2:1995 + A13:1996, CAN/CSA C22.2 No. 601.1-M90 (R1997), CAN/CSA C22.2 No. 601.1S1-94, and CAN/CSA C22.2 No. 601.1B-98 (National Differences for Canada), (except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1, Programmable Electronic Systems, IEC 60601-1-4)</p>
CE1.2	<p>The product was not investigated to the following standards or clauses:</p>	<p>Clause 36, Electromagnetic Compatibility (IEC 601-1-2), Clause 48, Biocompatibility (ISO 10993-1), Clause 52.1, Programmable Electronic Systems (IEC 601-1-4)</p>

CE1.3	The product is Classified only to the following hazards:	Shock, Fire,
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:	None
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 power supply has been evaluated as Class I with no applied parts, 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.	--
CF2.1	This component has been judged on the basis of the required spacings in the Standards for Medical Equipment, Part 1: General Requirements for Safety, UL60601-1, First Edition (2003) , IEC60601-1, Second Edition (1998) and CSA 22.2 No. 601.1, which covers the end use product for which the component is designed.	--
CF2.2	The component shall be installed in compliance with the enclosure, mounting, spacings, casualty markings and segregation requirements of the end-use application.	--
CF2.3	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.	--
CF2.4	The input/output are not acceptable for field connection, they are only intended for connection to mating connectors of internal wiring inside the end-use machine. The output circuits have not been evaluated for direct	--

	patient connection (Type B, BF or CF).	
CF2.5	The component should be properly bonded to the ground in the end-use equipment.	--
CF2.6	The temperature test was performed in a raised ambient of 50°C.	--
CF2.7	Leakage Current testing should be repeated in the end-product application.	--
CF2.8	The main Power Transformer (T6) and Bias Transformer (T7), comply with Class F (155°C) limits.	--
CF2.9	Additional fusing should be considered in the end product since this power supply was tested with only one internal fuse, rated T 12A, 250 V.	--
CF3	Humidity and Blocked Ventilation Cooling Abnormal Testing should be considered as part of the end-use application.	--