



VP Engineering
Ultra Level Tech Co Ltd
4TH FL 2 LANE 235 BAU-CHIAU RD
HSIN-TIEN DISTRICT
NEW TAIPEI
231 TAIWAN

Date: 2017/09/15
Subscriber: 252060001
PartySite: 8846
File No: E257331
Project No: 4788068610
PD No: 17Q08980
Type: R
PO Number:

Subject: **Procedure And/Or Report Material**

The following material resulting from the investigation under the above numbers is enclosed.

Issue

<u>Date</u>	<u>Vol</u>	<u>Sec</u>	<u>Pages</u>	<u>Revised Date</u>
2017/09/06	1	1	Add New Volume	
2017/09/06	1	1	Cert of Compliance	

PO: SPC PO no. EH/SPC-1707029-app

Inspections at your plant will be conducted under the supervision of MARSY MA, UL INSPECTION CENTER TAIPEI, UL INTERNATIONAL SERVICES LTD, 260 DA-YEH RD, 5TH FL, PEITOU, TAIPEI CITY, Taiwan, 112., PHONE: 2-2893-8033, FAX: 2-2897-8628, EMAIL: MARSY.MA@ul.com

Please file revised pages and illustrations in place of material of like identity. New material should be filed in its proper numerical order.

NOTE: Follow-Up Service Procedure revisions DO NOT include Cover Pages, Test Records and Conclusion Pages. Report revisions DO NOT include Authorization Pages, Indices, Section General Pages and Appendixes.

Please review this material and report any inaccuracies to UL's Customer Service Professionals. Contact information for all of UL's global offices can be found at <http://ul.com/aboutul/locations>.

If you'd like to receive updated materials FASTER, UL offers electronic access and/or delivery of this material. For more details, contact UL's Customer Service Professionals as shown above.

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CAM File

UL INSPECTION CENTER 818



File E257331

Vol 1

Auth. Page 1

Issued: 2017-09-15

Revised: 2017-09-15

FOLLOW-UP SERVICE PROCEDURE
(TYPE R)

COMPONENT - POWER SUPPLIES, MEDICAL AND DENTAL
(QQHM2,QQHM8)

Manufacturer: SEE ADDENDUM FOR MANUFACTURER LOCATIONS

Applicant: 8846 (Party Site)
Ultra Level Tech Co Ltd
(252060-001) 4TH FL 2 LANE 235 BAU-CHIAU RD
HSIN-TIEN DISTRICT
NEW TAIPEI
231 TAIWAN

Recognized Company: 8846 (Party Site)
SAME AS APPLICANT
(252060-001)

This Follow-Up Service Procedure authorizes the above Manufacturer(s) to use the marking specified by UL LLC, or any authorized licensee of UL LLC, including the UL Contracting Party, only on products when constructed, tested and found to be in compliance with the requirements of this Follow-Up Service Procedure and in accordance with the terms of the applicable service agreement with UL Contracting Party and any applicable Service Terms. The UL Contracting Party for Follow-Up Services is listed on addendum to this Follow-Up Service Procedure ("UL Contracting Party"). UL Contracting Party and UL LLC are referred to jointly herein as "UL."

UL further defines responsibilities, duties and requirements for both Manufacturers and UL representatives in the document titled, "UL Mark Surveillance Requirements" that can be located at the following web-site: <http://www.ul.com/fus> and in the document titled "UL and Subscriber Responsibilities" that can be located at the following website: <http://www.ul.com/responsibilities>. Manufacturers without Internet access may obtain the current version of these documents from their local UL customer service representative or UL field representative. For assistance, or to obtain a paper copy of these documents or the applicable Service Terms, please contact UL's Customer Service at <http://ul.com/aboutul/locations/>, select a location and enter your request, or call the number listed for that location.

The Applicant, the specified Manufacturer(s) and any Recognized Company in this Follow-Up Service Procedure must agree to receive Follow-Up Services from UL Contracting Party. If your applicable agreement is a Global Services Agreement ("GSA") with an effective date of January 1, 2012 or later and this Follow-Up Service Procedure is issued on or after that effective date, the Applicant, the specified Manufacturer(s) and any Recognized Company will be bound to a Service Agreement for Follow-Up Services upon the earliest by any Subscriber of use of the prescribed UL Mark, acceptance of the factory inspection, or payment of the Follow-Up Service fees which will incorporate such GSA, this Follow-Up Service Procedure and the Follow-Up Service Terms which can be accessed by clicking here: <http://www.ul.com/contracts/Terms-After-12-31-2011>. In all other events, Follow-Up Services will be governed by and incorporate the terms of your applicable service agreement and this Follow-Up Service Procedure.

It is the responsibility of the Recognized Company to make sure that only the products meeting the aforementioned requirements bear the authorized Marks of UL LLC, or any authorized licensee of UL LLC.

This Follow-Up Service Procedure contains information for the use of the above Manufacturer(s) and representatives of UL and is not to be used for any other purpose. It is provided to the Manufacturer with the understanding that it will be returned upon request and is not to be copied in whole or in part.

This Follow-Up Service Procedure, and any subsequent revisions, is the property of UL and is not transferable. This Follow-Up Service Procedure contains confidential information for use only by the above named Manufacturer(s) and representatives of UL and is not to be used for any other purpose. It is provided to the Subscribers with the understanding that it is not to be copied, either wholly or in part unless specifically allowed, and that it will be returned to UL, upon request.

Capitalized terms used but not defined herein have the meanings set forth in the GSA and the applicable Service Terms or any other applicable UL service agreement.

UL shall not incur any obligation or liability for any loss, expense or damages, including incidental, consequential or punitive damages arising out of or in connection with the use or reliance upon this Follow-Up Service Procedure to anyone other than the above Manufacturer(s) as provided in the agreement between UL LLC or an authorized licensee of UL LLC, including UL Contracting Party, and the Manufacturer(s).

UL LLC has signed below solely in its capacity as the accredited entity to indicate that this Follow-Up Service Procedure is in compliance with the accreditation requirements.

Bruce A. Mahrenholz
Director
North American Certification Program

LOCATION

(252060-001) 8846 (Party Site)
Ultra Level Tech Co Ltd
4TH FL 2 LANE 235 BAU-CHIAU RD
HSIN-TIEN DISTRICT
NEW TAIPEI
231 TAIWAN
Factory ID: None
UL Contracting Party for above site is: UL AG

Recognized Component Marking Data Page (RCMDP)

(FILE IMMEDIATELY AFTER AUTHORIZATION PAGE)

RECOGNIZED COMPONENT MARKING

Products Recognized under UL's Component Recognition Service are identified by marking elements consisting of:

1. The Recognized Company's identification specified in this document.
2. A catalog, model or other applicable product designation specified in the descriptive sections of this document.
3. The UL Recognized Component Mark shown below is optional unless required elsewhere in the Procedure.

Only those components, which actually bear the Marking, should be considered as being covered under the Recognition Program. The UL Listing or Classification Mark is not authorized for use on or in connection with Recognized Components.

Recognized Component Mark



Minimum size of the Recognized Component Mark is not specified as long as it is legible. Minimum height of the registered symbol ® shall be 3/64 inch but may be omitted if it is out of proportion to the Recognized Component Mark or not legible to the naked eye.

The manufacturer may reproduce the Mark electronically. Any decision regarding the acceptability of the manufacturer's Mark reproduction will be made at the Reviewing Office.

Recognized Component Marking Data Page (RCMDP)

(FILE IMMEDIATELY AFTER AUTHORIZATION PAGE)

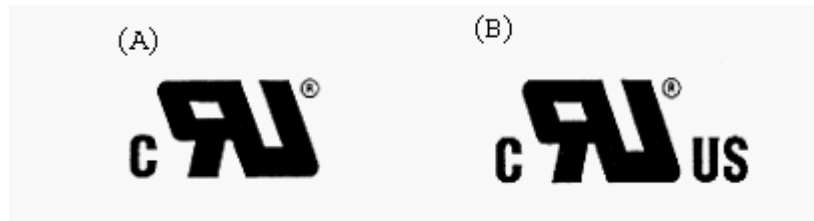
RECOGNIZED COMPONENT MARKING

Products Recognized under UL's Component Recognition Service are identified by marking elements consisting of:

1. The Recognized Company's identification specified in this document.
2. A catalog, model or other applicable product designation specified in the descriptive sections of this document.
3. The UL Recognized Component Mark shown below:
 - (A) Recognized only to Canadian safety requirements, or;
 - (B) Recognized to both U.S. and Canadian safety requirements.

Only those components, which actually bear the Marking, should be considered as being covered under the Recognition Program. The UL Listing or Classification Mark is not authorized for use on or in connection with Recognized Components.

Recognized Component Mark



Minimum size of the Recognized Component Mark is not specified as long as it is legible. Minimum height of the registered symbol ® shall be 3/64 inch but may be omitted if it is out of proportion to the Recognized Component Mark or not legible to the naked eye.

The manufacturer may reproduce the Mark electronically. Any decision regarding the acceptability of the manufacturer's Mark reproduction will be made at the Reviewing Office.

Models

PRL1103x-y,
where x = U, F, E
y = 12, 15, 24, 36, 48

PRL1103Dx-z
where x = U, F, E
z = 0512,1224

Section Report Date

1 2017-09-06

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) - Amendment 1 - Revision Date 2012/08/21. CAN/CSA-C22.2 No. 60601-1:14 - Edition 3 - Revision Date 2014/03
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8
Product:	Switching Power Supply
Model:	PRL1103x-y, where x = U, F, E y = 12, 15, 24, 36, 48 PRL1103Dx-z where x = U, F, E z = 0512,1224
Rating:	See Enclosure ID 7-02 for details I/P: 100-240Vac, 47-63Hz, 5.0-2.0A O/P: For Model PRL1103x-12: 12-13.8Vdc, 25A (300W) or 12.5A (150W) For Model PRL1103x-15: 14-16Vdc, 21.43A (300W) or 10.71A (150W) For Model PRL1103x-24: 23-28Vdc, 13.04A (300W) or 6.52A (150W) For Model PRL1103x-36: 35-43Vdc, 8.57A (300W) or 4.29A (150W) For Model PRL1103x-48: 44-52Vdc, 6.82A (300W) or 3.41A (150W) For Model PRL1103Dx-0512: V1: +5Vdc, 24A, V2: +12Vdc, 13.33A, total 240W; or V1: +5Vdc, 12A, V2: +12Vdc, 6.67A, total 120W For Model PRL1103Dx-1224: V1: +12Vdc, 13.33A, V2: +24Vdc, 6.67A, total 240W; or V1: +12Vdc, 6.67A, V2: +24Vdc, 3.33A, total 120W Output condition A (300W or 240W) for unit Forced Airflow (25 CFM) or provided with built-in fan cooling condition. Output condition B (150W or 120W) for unit convection condition. (Condition B for Model with x = U only) See Enclosure ID 7-02 for details
Applicant Name and Address:	ULTRA LEVEL TECH CO LTD 4TH FL 2 LANE 235 BAU-CHIAU RD HSIN-TIEN DISTRICT NEW TAIPEI 231 TAIWAN

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.

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

Prepared by: Sun Yi

Reviewed by: Zila Pi

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 equipment is a switching type power supply which electronic components mounted on PWB and housed in Metal chassis for Class I medical electrical equipment.

Two MOPP insulations were provided between primary and secondary, one MOPP was provided between primary and PE.

Model Differences

All models are similar except for output ratings, chassis shape, main supply connection, DC Fan, Secondary winding of Transformer (T1), secondary circuit and model designation.

Model designation nomenclatures:

PRL1103x-y and PRL1103Dx-z

"x" can be U, F or E to indicate the different chassis shape.

U = U-chassis (3.2"W x 5"L x 1.5"H)

Main supply connection can be used Primary Connector or Terminal Block.

F = U-chassis (3.2"W x 5"L x 1.5"H) with fan cover.

Two fan covers.

Option 1: Fan secured under the cover (3.2"W x 5"L x 2"H);

Option 2: Fan secured upon the cover (3.2"W x 5"L x 2.23"H).

Main supply connection can be used Primary Connector or Terminal Block.

E = Enclosed chassis with a built-in fan in the front chassis (3.2"W x 6.5"L x 1.6"H).

Main supply connection can be used Appliance Inlet or Terminal Block.

"y" can be 12, 15, 24, 36 or 48 to indicate different single output rating.

"z" can be 0512, 1224 to indicate dual output rating.

Note: When x = U, the power supply can be provided with external 25 CFM forced airflow for different output ratings, see Enclosure ID 7-02 for details.

Technical Considerations

- Classification of installation and use: For built-in. Recognized power supply, installation should be considered in end use.

- Device type (component/sub-assembly/ equipment/ system): Component
- Intended use (Including type of patient, application location): Switching type power supply for general use with medical electrical equipment.
- Mode of operation: Continuous
- Supply connection: Primary Connector or Terminal Block or Appliance Inlet (To be evaluated in end product)
- Accessories and detachable parts included: None
- Other options include: None
- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) - Amendment 1 - Revision Date 2012/08/21 (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance); CAN/CSA-C22.2 No. 60601-1:14 - Edition 3 - Revision Date 2014/03 (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
- 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 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 clearance in the Standards for Medical Electrical Equipment, Clause 8.9 of ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) - Amendment 1 - Revision Date 2012/08/21 (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) and CAN/CSA-C22.2 No. 60601-1 (2014) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada) that cover the end-use product for which the component was designed.
- This power supply has been evaluated as a Class I, 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 I equipment.
- This power supply was tested on a 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The power supply was evaluated to MOPP among Primary, Secondary and Protective Earth. Two MOPP provided between Primary to Secondary, One MOPP provided between Primary and PE; see insulation diagram for details.
- 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°C) and a Class F (155°C) insulation system; (CT1, DT1, T3) employs a Class B (130°C) insulation system.
- The maximum ambient temperature of the product is 50°C for output full load.
- "Voltage or charge limitation" may need to reconsider if additional EMC filter is provided between appliance inlet/ power cord to the product.
- The following tests shall be performed in the end-product evaluation: Temperature Test, Dielectric Voltage Withstand Tests, and Leakage Current Test.
- The reference voltage for Dielectric Voltage Test in End Product: 348Vrms, 680Vpk for T1.
- This equipment is a Built-in power supply, a suitable Electrical, Mechanical or Fire enclosure must be provided as part of the end application.
- The accessibility of output connectors, insulating materials and temperatures shall be considered in the end use product.
- The Durability of Marking Test and Legibility of Markings for Label artwork will be considered in end system.
- The end-product evaluation shall ensure that the requirements related to series number and manufacturer date, Clause 7.2 are met.
- Test corner shall be considered as part of the end product evaluation.

- PE Terminal Marking shall be evaluated in Class I end product applications.
- Overcurrent releases of adequate breaking capacity must be employed in the end product.

Additional Information

Following Clauses were not evaluated by Underwriters Laboratories Inc., suitable evidence of compliance should exist as required by national or regional regulations.



- Clause 11.7: Biocompatibility
- Clause 10.5, 17: Electromagnetic Compatibility
- Clause 12.2: Usability

US/CANADA deviations were provided in Enclosure - National Differences.

Additional Standards

ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) - Amendment 1
 - Revision Date 2012/08/21.CAN/CSA-C22.2 No. 60601-1:14 - Edition 3 - Revision Date 2014/03

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	
Direct current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power and frequency.
Fuses	Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure)

Special Instructions to UL Representative

N/A

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
All models	No exemption	No exemption	Exemption

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
N/A	N/A	N/A	N/A

Certificate



Certificate no.

TA 50233409 01

License Holder:

Ultra Level Tech. Co., Ltd.
4F. No.2, Lane 235, Bau-Chiau Road
Hsin-Tien Dist., New Taipei City
231
Taiwan

Manufacturing Plant:

Ultra Level Tech. Co., Ltd.
4F. No.2, Lane 235, Bau-Chiau Road
Hsin-Tien Dist., New Taipei City
231
Taiwan

Test report no.: ZTW1-LinPr 10036366 001

Client Reference: EH/SPC-1203061-app

Tested to: IEC 60601-1:2005
EN 60601-1:2006

Certified Product: (Switching Power Supply)

License Fee - Units

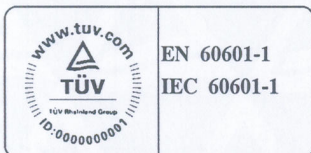
Type Designation	: PRL1103x-y (RL)	10
x stands for	: U, E or F	1
y stands for	: 12, 15, 24, 36 or 48	1
Rated Voltage	: AC 100-240V, 47-63Hz	
Rated Current	: 5-2A	
Output Voltage	: see constructional dataform	
Output Current	: see constructional dataform	
max. Output Power	: see constructional dataform	
max. Ambient Temperature:	50°C	
Protection Class	: I	

This certificate is valid for maximum 5 years.

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Appendix: 1

Licensed Test mark:



TÜV Rheinland Taiwan Ltd.

Signature

Dipl.-Ing. W. Hsu



Date of Issue

(day/mo/yr)
20/07/2012

Certificate



Certificate no.

TA 50233409 02

License Holder:

Ultra Level Tech. Co., Ltd.
4F. No.2, Lane 235, Bau-Chiau Road
Hsin-Tien Dist., New Taipei City
231
Taiwan

Manufacturing Plant:

Ultra Level Tech. Co., Ltd.
4F. No.2, Lane 235, Bau-Chiau Road
Hsin-Tien Dist., New Taipei City
231
Taiwan

Test report no.: ZTW1-LinPr 10036366 001

Client Reference: EH/SPC-1203061-app

Tested to: IEC 60601-1:2005
EN 60601-1:2006

Certified Product: (Switching Power Supply)

License Fee - Units

as page 01

Addition

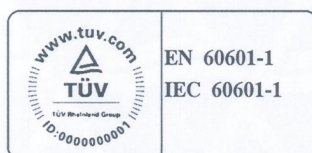
Type Designation	: PRL1103Dx-z (RL)	1
x stands for	: U, E or F	1
z stands for	: 0512 or 1224	1

This certificate is valid for maximum 5 years.

3

Appendix: 1

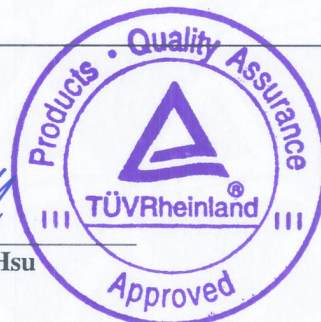
Licensed Test mark:



TÜV Rheinland Taiwan Ltd.

Signature

W. Hsu
Dipl.-Ing. W. Hsu



Date of Issue

(day/mo/yr)
20/07/2012

Certificate



Certificate no.

TA 50233409 05

License Holder:

Ultra Level Tech. Co., Ltd.
4F. No.2, Lane 235, Bau-Chiau Road
Hsin-Tien Dist., New Taipei City
231
Taiwan

Manufacturing Plant:

Ultra Level Tech. Co., Ltd.
4F. No.2, Lane 235, Bau-Chiau Road
Hsin-Tien Dist., New Taipei City
231
Taiwan

Test report no.: ZTW1-LinPr 10036366 005

Client Reference: EH/SPC-07072047-PRL1

Tested to: IEC 60601-1:2005+A1
EN 60601-1:2006+A11+A1+A12

Certified Product: (Switching Power Supply)

License Fee - Units

as page 01

Change

Test Requirement : see above

This certificate is valid for maximum 5 years.

Appendix: 1

Licensed Test mark:



TÜV Rheinland Taiwan Ltd.

Signature

Dipl.-Ing. W. Hsu



Date of Issue

(day/mo/yr)

22/09/2017

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

CB TEST CERTIFICATE

Product	Switching Power Supply
Name and address of the applicant	Ultra Level Tech. Co., Ltd. 4F. No.2, Lane 235, Bau-Chiau Road Hsin-Tien Dist., New Taipei City, Taiwan 231
Name and address of the manufacturer	Ultra Level Tech. Co., Ltd. 4F. No.2, Lane 235, Bau-Chiau Road Hsin-Tien Dist., New Taipei City, Taiwan 231
Name and address of the factory	Ultra Level Tech. Co., Ltd. 4F. No.2, Lane 235, Bau-Chiau Road Hsin-Tien Dist., New Taipei City, Taiwan 231
Ratings and principal characteristics	AC 100-240V; 47-63Hz; 5-2A; Class I; for output ratings refer to test report page 10
Trademark (if any)	RL
Customer's Testing Facility (CTF) Stage used	N/A
Model / Type Ref.	PRL1103x-y, PRL1103Dx-z (x = U, E or F to denote the cooling options and metal chassis construction; y = 12, 15, 24, 36 or 48 and z = 0512 or 1224 to denote the output rating)
Additional information (if necessary may also be reported on page 2)	Models differ in model name, o/p construction, o/p circuits/ PCB and chassis, construction of the main transformer T1, optionally used appliance inlet and terminal blocks or connectors; for details see test report
A sample of the product was tested and found to be in conformity with	IEC 60601-1:2005+A1 for national deviations see test report
As shown in the Test Report Ref. No. which forms part of this Certificate	50092763 001

This CB Test Certificate is issued by the National Certification Body



TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg, Germany
Phone + 49 221 806-1371
Fax + 49 221 806-3935
Mail: cert-validity@de.tuv.com
Web: www.tuv.com



Date: 22.09.2017


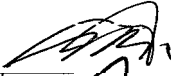

Signature: Dipl.-Ing. W. Hsu



Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.....:	50092763 001
Date of issue	September 6 th , 2017
Total number of pages.....:	115
CB Testing Laboratory.....:	TÜV Rheinland Taiwan, Taichung Laboratory
Address	No. 9, Ln. 36, Sec. 3, Minsheng Rd., Daya District, Taichung City 428, Taiwan
Applicant's name.....:	Ultra Level Tech. Co., Ltd.
Address	4F. No.2, Lane 235, Bau-Chiau Road, Hsin-Tien Dist., New Taipei City, 231 Taiwan
Test specification:	
Standard	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	CB Scheme
Non-standard test method.....:	None
Test Report Form No.....:	IEC60601_1K
Test Report Form Originator	UL(US)
Master TRF	2015-11
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General disclaimer: The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	

Test item description	Switching Power Supply	
Trade Mark		
Manufacturer	Same as applicant	
Model/Type reference	PRL1103x-y, PRL1103Dx-z (x = U, E, F; y = 12, 15, 24, 36, 48; z = 0512 or 1224)	
Ratings	Input: AC 100-240V, 47-63Hz, 5 - 2A Output: Refer to page 10	
Testing procedure and testing location:		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	
Testing location/ address		Same as on the cover page.
<input type="checkbox"/>	Associated CB Testing Laboratory:	
Testing location/ address		
Tested by (name, function, signature)		Price Lin, Engineer 
Approved by (name, function, signature)		Jon S.C. Lin, Technical Certifier 
<input type="checkbox"/>	Testing procedure: CTF Stage 1:	
Testing location/ address		
Tested by (name, function, signature)		
Approved by (name, function, signature)		
<input type="checkbox"/>	Testing procedure: CTF Stage 2:	
Testing location/ address		
Tested by (name, function, signature)		
Witnessed by (name, function, signature)		
Approved by (name, function, signature)		
<input type="checkbox"/>	Testing procedure: CTF Stage 3:	
<input type="checkbox"/>	Testing procedure: CTF Stage 4:	
Testing location/ address		
Tested by (name, function, signature)		
Witnessed by (name, function, signature)		
Approved by (name, function, signature)		

List of Attachments (including a total number of pages in each attachment):	
<ul style="list-style-type: none"> - Photo Documentation (10 pages); - Technical Documentation (9 pages); - Measurement Section (12 pages) 	
Summary of testing	
<p>Tests performed (name of test and test clause):</p> <p>All applicable tests as described throughout this test report and in the Measurement Section were performed.</p> <ul style="list-style-type: none"> • Tests were performed on models below to represent the other models. <ul style="list-style-type: none"> • For model with single output: PRL1103U-12, PRL1103U-48, PRL1103E-12, PRL1103E-48, PRL1103F-12 and PRL1103F-48. • For model with dual output: PRL1103DU-0512, PRL1103DU-1224, PRL1103DE-0512, PRL1103DE-1224, and PRL1103DF-0512. • If not otherwise specified, PRL1103U-y and PRL1103DU-z tests were performed with external forced air-flow. For the tests with conventional cooling, the output load is 50% of rated load. • The maximum specified operational ambient temperature is +50°C. • The test samples were pre-production without serial number. The models used for testing as representative for the whole series of models are described in the attached test data tables. 	<p>Testing location:</p> <p>All tests as described within this test report and as described in the Measurement Section were performed at the laboratory described on page 2.</p>
Summary of compliance with National Differences	
<p>List of countries addressed: N/A</p> <p><input checked="" type="checkbox"/> The product fulfils the requirements of EN 60601-1: 2006 + A11: 2011 + A1: 2013 + A12: 2014</p>	

VERIFICATION OF COMPLIANCE

Issue Date: July 16, 2021
Applicant: ULTRA LEVEL TECH CO., LTD.
Address: 4F, No.2, Lane 235, Bau-Chiau Road, Hsin-Tien District, New Taipei City 231, Taiwan, R.O.C.
Manufacturer: ULTRA LEVEL TECH CO., LTD.
Address: 4F, No.2, Lane 235, Bau-Chiau Road, Hsin-Tien District, New Taipei City 231, Taiwan, R.O.C.
Contact Information: Web: www.ultralevel.com.tw
TEL#: 886-2-29180118
E-mail#: fiona@ultralevel.com.tw
Product: Switching Power Supply
Brand Name/Trade Mark: N/A
Model/Type: PRL1103x-y (x = U, F or E ; y= 12, 15, 24, 36 or 48)
PRL1103Dx-y (x = U, F or E ; y= 0512 or 1224)
Added Model(s): N/A
Applicable Standards: **EN 60601-1-2: 2015+A1: 2021**
EN 55011: 2016+A1: 2017+A11: 2020 (Class B)
EN 61000-3-2: 2014
EN 61000-3-3: 2013+A1: 2019
IEC 61000-4-2: 2008
IEC 61000-4-3: 2020
IEC 61000-4-4: 2012;
IEC 61000-4-5: 2014 +A1: 2017
IEC 61000-4-6: 2013+C1: 2015
IEC 61000-4-8: 2009
IEC 61000-4-11: 2020+C1: 2020
Test Laboratory: Compliance Certification Services Inc.
Tainan Lab
No.8, Jiucengling, Xinhua Dist., Tainan City, Taiwan
Test Report No. : T210629N03-E, dated on July 16, 2021

Conclusion:

Based upon a review of the Test Report(s), the tested sample of the product mentioned above is deemed to comply with the requirements of the above standards.

Note: This verification is only valid for the product and configuration described and in conjunction with the test report as detailed above.

Authorised Signatory:

Compliance Certification Services Inc.

Jeter Wu

Manager

FM-023A-R01

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