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.....:	**T223-0163/12**
Date of issue .....:	**2012-06-06** .....
Total number of pages.....:	**389 pages** .....
CB Testing Laboratory.....:	**SIQ – Slovenian Institute of Quality and Metrology**
	Testing Laboratory is accredited by Slovenian Accreditation, Reg. No.: LP-009
Address .....:	**Tržaška cesta 2, 1000 Ljubljana, Slovenia**
Applicant's name.....:	**Arch Electronics Corp.**
Address .....:	**3F., No. 79, Sec. 1, Hsin Tai Wu Rd., Sijhih City, Taipei County 221, Taiwan**
Test specification:	
Standard .....:	**IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)**
Test procedure.....:	**CB Scheme**
Non-standard test method……..:	**N/A**
Test Report Form No.....:	**IEC60601_1G**
Test Report Form Originator.....:	**Underwriters Laboratories Inc.**
Master TRF .....:	**Dated 2010-11**

Copyright © 2010 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.

This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo shall be removed

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description .....:	**Switching Power Supply for building-in**
Trade Mark .....:	TDK·Lambda
Manufacturer.....:	**Arch Electronics Corp.**
	3F., No. 79, Sec. 1, Hsin Tai Wu Rd., Sijhih City, Taipei County 221, Taiwan

Model/Type reference ..... : **KMx15-y**

''x'' can be S, D or T

S= Single output

D= Dual output

T= Triple output

''y'' can be 3P3, 5, 7P35, 9, 12, 15, 24, 55, 1212, 1515, 51212 or 51515

Ratings ..... : **I/P: 100-240 Vac; 47-63 Hz; 0,32-0,17 A**

O/P:

Model Name	Output Ratings (output dc voltage / output current)
KMS15-3P3	3,3 V / 3 A
KMS15-5	5 V / 3 A
KMS15-7P35	7,35 V / 2,04 A
KMS15-9	9 V / 1,666 A
KMS15-12	12 V / 1,25 A
KMS15-15	15 V / 1 A
KMS15-24	24 V / 0,625 A
KMD15-55	+ 5 V / 1,5 A; - 5 V / 1,5 A
KMD15-1212	+ 12 V / 0,625 A; - 12 V / 0,625 A
KMD15-1515	+ 15 V / 0,5 A; - 15 V / 0,5 A
KMT15-51212	+ 5 V / 2 A; + 12 V / 0,2 A; - 12 V / 0,2 A
KMT15-51515	+ 5 V / 2 A; + 15 V / 0,15 A; - 15 V / 0,15 A

Testing procedure and testing location:	
☒ CB Testing Laboratory:	SIQ – Slovenian Institute of Quality and Metrology
Testing location/ address ..... :	Tržaška cesta 2, 1000 Ljubljana, Slovenia
☐ Associated CB Test Laboratory:	
Testing location/ address ..... :	
Tested by (name + signature).. :	Janez Vidmar
Approved by (+ signature)..... :	Boštjan Glavič
☐ Testing procedure: TMP	
Tested by (name + signature).. :	
Approved by (+ signature)..... :	
Testing location/ address ..... :	
☐ Testing procedure: WMT	
Tested by (name + signature).. :	
Witnessed by (+ signature)..... :	
Approved by (+ signature)..... :	
Testing location/ address ..... :	
☐ Testing procedure: SMT	
Tested by (name + signature).. :	
Approved by (+ signature)..... :	
Supervised by (+ signature) .... :	
Testing location/ address ..... :	
☐ Testing procedure: RMT	
Tested by (name + signature).. :	
Approved by (+ signature)..... :	
Supervised by (+ signature) .... :	
Testing location/ address ..... :	

List of Attachments (including a total number of pages in each attachment):

1. **Test Report (215 pages)**
2. **National Differences to IEC 60601-1:2005 – Enclosure No. 1 (11 pages)**
3. **Photo documentation – Enclosure No. 2 (15 pages)**
4. **Schematics, layouts and transformer drawings – Enclosure No. 3 (148 pages)**

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
See next pages **The risk management requirements of the standard were not addressed.**	**SIQ – Slovenian Institute of Quality and Metrology** **Tržaška cesta 2, 1000 Ljubljana, Slovenia**

Summary of compliance with National Differences (See enclosure No. 1 for details)

List of countries addressed:

- US NATIONAL DIFFERENCES to IEC 60601-1 Third edition
National standard ANSI/AAMI ES60601-1: 2005

- CANADA NATIONAL DIFFERENCES to IEC 60601-1 Third edition
National standard CAN/CSA-C22.2 No. 60601-1:08

- SWITZERLAND NATIONAL DIFFERENCES to IEC 60601-1 Third edition
National standard SN EN 60601-1:06

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

(MTC-3.3S)

(MTC-5S)

(MTC-7.35S)

(MTC-9S)

(MTC-12S)

(MTC-15S)

(MTC-24S)

(MTC-5D)

(MTC-12D)

(MTC-15D)

(MTC-5S12D)

(MTC-5S15D)

Tests performed (name of test and test clause):		Verdict
4.11	Power Input	P
7.1.3	Durability of marking	P
8.4	Limitation of voltage current and energy	P
8.5.5.	Defibrillation- proof applied parts	N/A
8.6.4.	Impedance and current- carrying capability of protective earth connections	N/A
8.7.4.5	Earth Leakage Current	N/A
8.7.4.6.	Touch Current	P
8.7.4.7.	Patient Leakage Current	N/A
8.7.4.8.	Patient Auxiliary Current	N/A
8.7.4.9.	Multiple Patient Connections	N/A
8.8.3A	Dielectric Strength test of solid insulation materials with safety functions- MOOP	N/A
8.8.3B	Dielectric Strength test of solid insulation materials with safety functions- MOPP	P
8.9.2	Short circuits in Mains part over creepage and clearance distances	P
8.9.3.2	Thermal Cycling Test on one sample of insulation compound forming solid insulation between conductive parts	N/A
8.9.3.4	Thermal Cycling test on one Sample of Cemented joint	N/A
9.2.2.2	Measurement of gap “a” according to table 20 (ISO 13452:1996)	N/A
10.1.1	Measurement of X- radiation	N/A
11.1	Excessive temperatures in ME EQUIPMENT	P
11.2.2.1	Existence of ignition sources	N/A
13.1	Power or energy dissipation	N/A
13.2	Single Fault conditions	P
15.3	Mechanical Strength test	P
15.4.6	Actuating parts of controls	N/A
15.5.1.2	Transformer short circuit	P
15.5.1.3	Transformer overload	P
15.5.2	Transformer dielectric strength after humidity preconditioning of 5.7	P
--	Working voltage Measurement	P
--	Evaluation of voltage limiting components in SELV circuits	P

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	**Power supply unit is intended for building-in and complies with the requirements of Class II construction.**
Device type (component/sub-assembly/ equipment/ system) ..... :	**Component (power supply unit intended for building-in).**
Intended use (Including type of patient, application location) ..... :	**EUT is intended to provide power to medical devices with isolation grade MOPP.**
Mode of operation ..... :	**Continuous operation**
Supply connection	**Power supply unit is intended for building-in (primary and secondary pins shall be soldered within end medical product)**
Accessories and detachable parts included ..... :	**No accessories and detachable parts included.**
Other options include ..... :	**No other options included**
Testing	
Date of receipt of test item(s) .....:	**2011-12-15**
Dates tests performed .....:	**From 2012-01-09 to 2012-05-23**
Possible test case verdicts:	
- test case does not apply to the test object .....:	**N/A**
- test object does meet the requirement .....:	**Pass (P)**
- test object was not evaluated for the requirement .....:	**N/E**
- test object does not meet the requirement .....:	**Fail (F)**
Abbreviations used in the report:	
- normal condition .....: N.C.	**- single fault condition ..... : S.F.C.**
- means of Operator protection .....: MOOP	**- means of Patient protection ... : MOPP**
General remarks:	
"(see Attachment #)" refers to additional information appended to the report.	
"(see appended table)" refers to a table appended to the report.	
The tests 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 testing laboratory.	
List of test equipment must be kept on file and available for review.	
Additional test data and/or information provided in the attachments to this report.	
Throughout this report a ☒ comma / ☐ point is used as the decimal separator.	

Manufacturer's Declaration per sub-clause 6.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ **Yes** ☒ **Not applicable**
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) ..... :	**Arch Electronics Corp.** **3F., No. 79, Sec. 1, Hsin Tai Wu Rd., Sijhih City, Taipei County 221, Taiwan**

General product information:

EUT is medical power supply unit intended for building-in provided with a single power output and with universal input range 100-240 Vac.

Power supply unit is provided with plastic enclosure and additionally filled with non-conductive insulation compound to increase rigidity of the power supply unit. Clearance and creepage distances not rely on insulation compounds; therefore thermal cycling not performed.

Power supply unit is provided with input and output pins intended for soldering to the PCB within end medical product.

In model designation KMx15-y, ''x'' can be S, D or T (S= Single output, D= Dual output, T= Triple output), ''y'' can be 3P3, 5, 7P35, 9, 12, 15, 24, 55, 1212, 1515, 51212 or 51515, which is used to indicate different output.

PCB with dimension 60 mm by 41 mm is used. There are totally 3 different layout of main PCB.

Circuit design in primary circuit of all models is identical. Circuit design in secondary circuit of all models is similar except for different design and sets of regulation circuits for multiple outputs.

All the transformers have similar separation construction, transformer construction details of model KMx15-y is specified in Enclosure No. 2.

Compliance with IEC / EN 60601-1-2 shall be evaluated during the end system evaluation.

Summary of testing:

The risk management requirements of the standard were not addressed. The power supply tested in this test report is only component level power supply. Power supply unit is intended for building-in. Risk management shall be addressed to the end type medical equipment.

Essential performance shall be determined within the end medical equipment; however for this medical power supply essential performance is considered MOPP. MOPP is tested within this test report.

The component was tested according to the standard IEC 60601-1:2005 (3rd Edition) and/or EN 60601-1:2006.

The unit is medical power supply unit intended for building-in.

The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).

The unit provides internally one primary fuse. Primary fuse not accessible due the power supply unit is additionally filed with insulation compound. See list of critical components for details.

Power supply unit was evaluated only for Means of Patient Protection (MOPP):

- **2 x MOPP between primary and secondary circuit**
- **2 x MOPP between primary and external plastic enclosure surface**

Secondary output circuit is separated from mains by reinforced insulation and rated SELV. The output does not provide hazard energy level.

Power supply is provided with user instruction related to the user and technical specification related to the service personnel.

The power supply is rated as class II (provided in fully plastic enclosure) construction.

The transformer T1 provides reinforced insulation. This transformer is built up to fulfil the requirement of insulation class A. See also list of safety critical components.

The equipment has been evaluated for use in a Pollution Degree 2 and overvoltage category II environment and a maximum altitude of 5000 m.

Multiplication factor for required clearance distance was 1,29 due the use up to 5000 meters altitude.

Power supply unit is provided with plastic enclosure made by non-flammable material UL94 V-0. See also list of safety critical components.

Cleaning and other applicable tests shall be considered within end product investigation.

The power supply in maintenance free.

The power supply is intended for operating at ambient temperature up to 50°C.

The unit shall not be used for use in an oxygen rich environment.

The unit it is not intended to be use with flammable anaesthetics and not intended for use in conjunction with flammable agents.