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.....:	**T223-0384/11**
Date of issue .....:	**2012-01-09** .....
Total number of pages.....:	**403 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**

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 ..... : **KMx40-y**

"x" can be S, D or T

S= Single output

D= Dual output

T= Triple output

"y" can be 3P3, 5, 9, 12, 15, 24, 55, 1212, 1515, 512, 524, 51212 or 51515

Ratings ..... : **I/P: 100-240 Vac; 47-63 Hz; 0,8-0,4 A**

O/P:

Model Name	Output Ratings (output dc voltage / output current)
KMS40-3P3	3,3 V / 8 A
KMS40-5	5 V / 8 A
KMS40-9	9 V / 4,444 A
KMS40-12	12 V / 3,333 A
KMS40-15	15 V / 2,666 A
KMS40-24	24 V / 1,667 A
KMD40-55	+5 V / 4 A, -5 V / 4 A
KMD40-1212	+12 V / 1,666 A, -12 V / 1,666 A
KMD40-1515	+15 V / 1,333 A, -15 V / 1,333 A
KMD40-512	+5 V / 5 A, +12 V / 1,25 A
KMD40-524	+5 V / 5 A, +24 V / 0,625 A
KMT40-51212	+5 V / 5 A, +12 V / 0,6 A, -12 V / 0,6 A
KMT40-51515	+5 V / 5 A, +15 V / 0,5 A, -15 V / 0,5 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)..... :	Gregor Schoss
☐ 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 (220 pages)**
2. **National Differences to IEC 60601-1:2005 – Enclosure No. 1 (11 pages)**
3. **Photo documentation – Enclosure No. 2 (12 pages)**
4. **Schematics, layouts and transformer drawings – Enclosure No. 3 (160 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

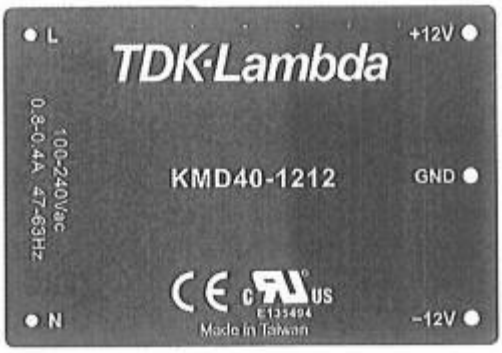
- CANADA NATIONAL DIFFERENCES to IEC 60601-1 Third edition
National standard CAN/CSA-C22.2 No. 60601-1:08

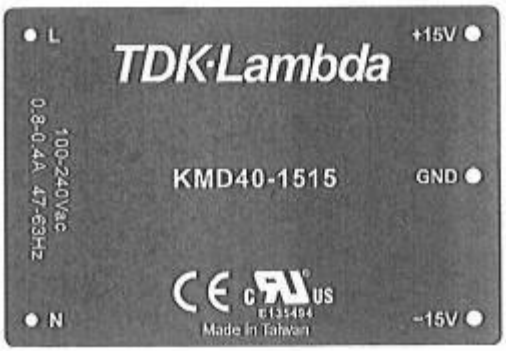
- SWITZERLAND NATIONAL DIFFERENCES to IEC 60601-1 Third edition
National standard SN EN 60601-1:06

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.


L
TDK·Lambda
+5V
100-240Vac
0.8-0.4A 47-63Hz
KMD40-55
GND
E135494
Made in Taiwan
N
-5V


L
TDK·Lambda
+12V
100-240Vac
0.8-0.4A 47-63Hz
KMD40-1212
GND
E135494
Made in Taiwan
N
-12V


L
TDK·Lambda
+15V
100-240Vac
0.8-0.4A 47-63Hz
KMD40-1515
GND
E135494
Made in Taiwan
N
-15V


L
TDK·Lambda
+24V
+5V
100-240Vac
0.8-0.4A 47-63Hz
KMD40-524
+24V
GND
+5V
GND
E135494
Made in Taiwan
N


L
TDK·Lambda
+12V
+5V
100-240Vac
0.8-0.4A 47-63Hz
KMD40-512
+12V
GND
+5V
GND
E135494
Made in Taiwan
N


L
TDK·Lambda
+15V
+5V
100-240Vac
0.8-0.4A 47-63Hz
KMT40-51515
±15V
GND
+5V
GND
E135494
Made in Taiwan
N
-15V


L
TDK·Lambda
+12V
+5V
100-240Vac
0.8-0.4A 47-63Hz
KMT40-51212
±12V
GND
+5V
GND
E135494
Made in Taiwan
N
-12V

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) .....:	**2011-10-05**
Dates tests performed.....:	**From 2011-10-05 to 2011-12-27**
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.