



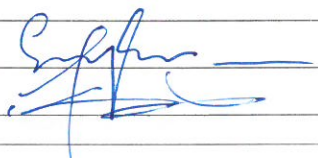

Test Report issued under the responsibility of:



<b>TEST REPORT</b> <b>IEC 60601-1</b> <b>Part 1: General requirements for basic safety and essential performance</b>	
<b>Report Number.</b> .....	50077301 001
<b>Date of issue</b> .....	2017-08-09
<b>Total number of pages</b> .....	149
<b>Name of Testing Laboratory preparing the Report</b> .....	TÜV Rheinland Shanghai Co., Ltd. No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China
<b>Applicant's name</b> .....	TDK-Lambda Corp. Nagaoka Technical Center
<b>Address</b> .....	2704-1 Settaya-machi, Nagaoka-shi, Niigata 940-1195, Japan
<b>Test specification:</b>	
<b>Standard</b> .....	IEC 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1 (2012 reprint)
<b>Test procedure</b> .....	CB Scheme
<b>Non-standard test method</b> .....	N/A
<b>Test Report Form No.</b> .....	IEC60601_1J_PS
<b>Test Report Form(s) Originator</b> .....	UL(US)
<b>Master TRF</b> .....	2014-09
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<b>General disclaimer:</b> 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..... :	<b>TDK-Lambda</b>
Manufacturer .....	Same as applicant
Model/Type reference..... :	CUS60M-zzxxxxxxx; CME60A-zzxxxxxxx (zz = 5,12,15,18,24,36 or 48; xxxxxx = A, U, ADJ, M, CO, SF, other alphanumeric character) Refer to page 10 for definition of variables
Ratings..... :	AC input: See the model list on pages 8-9 for details AC input: See the model list on pages 8-9 for details

**Testing procedure and testing location:**

<input checked="" type="checkbox"/> <b>CB Testing Laboratory:</b>	TÜV Rheinland Shanghai Co., Ltd.	
Testing location/ address .....	No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China	
<input type="checkbox"/> <b>Associated CB Testing Laboratory:</b>		
Testing location/ address .....		
Tested by (name + signature)..... :	Sunny Sun	
Approved by (name + signature)..... :	Mark Chen	
<input type="checkbox"/> <b>Testing procedure: TMP/CTF Stage 1:</b>		
Testing location/ address .....		
Tested by (name + signature)..... :		
Approved by (name + signature)..... :		
<input type="checkbox"/> <b>Testing procedure: WMT/CTF Stage 2:</b>		
Testing location/ address .....		
Tested by (name + signature)..... :		
Witnessed by (name + signature) .....		
Approved by (name + signature)..... :		
<input type="checkbox"/> <b>Testing procedure: SMT/CTF Stage 3 or 4:</b>		
Testing location/ address .....		
Tested by (name + signature)..... :		
Witnessed by (name + signature) .....		
Approved by (name + signature)..... :		
Supervised by (name + signature)..... :		

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

- ATTACHMENT 1 - National Differences (18 pages)
- ATTACHMENT 2 - Photo documentation (6 pages)
- ATTACHMENT 3 - Technical documentation (17 pages)

Note: Total number of pages in each attachment is indicated in individual attachment.

**Summary of testing:**

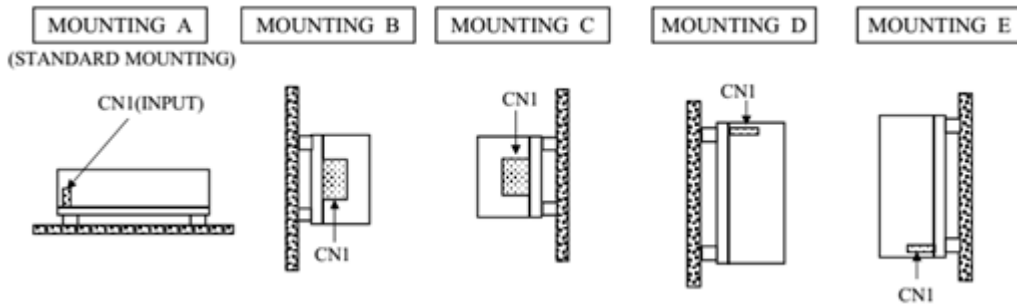
All applicable tests as described in Test Case and Measurement Sections were performed.

The maximum specified operation ambient temperature is 70°C.

Specified ambient temperature for operation is according to manufacturer's specification.(see chart of convection cooling on following)

The load conditions used during testing: Maximum normal load for this equipment is the operation with the maximum specified DC-load with maximum power condition according to the manufacturer specified.

**MOUNTING DIRECTIONS**



**Derating Curve:**

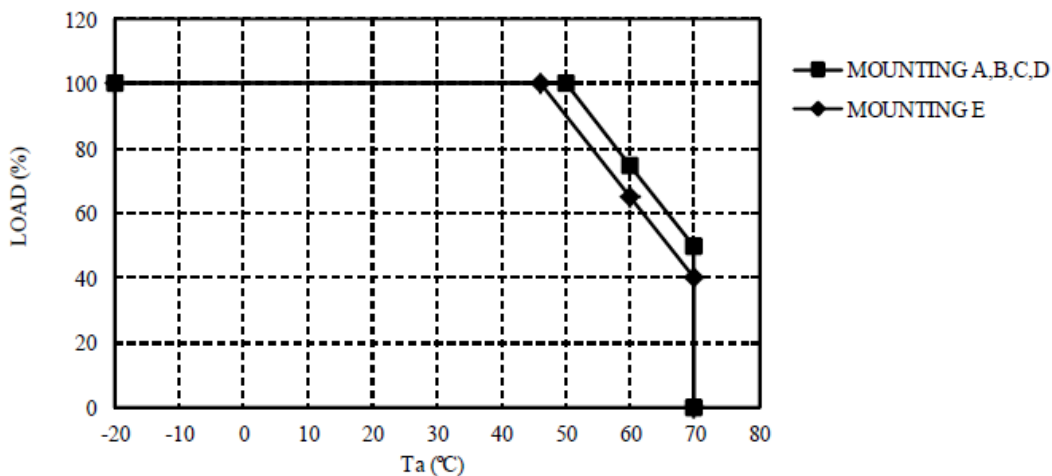
For CUS60M (excluding CUS60M-/A) series

Convection Cooling: Mounting A,B,C,D

Ta (°C)	Load (%)
-20 - +50	100
60	75
70	50

Convection Cooling: Mounting E

Ta (°C)	Load (%)
-20 - +46	100
60	65
70	40



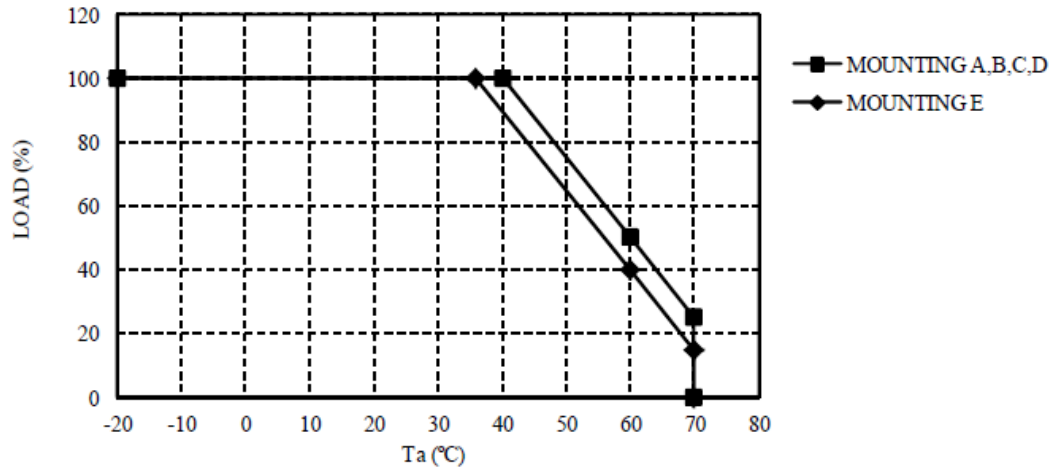
For CUS60M-/A series

Convection Cooling: Mounting A,B,C,D

Ta (°C)	Load (%)
-20 - +40	100
60	50
70	25

Convection Cooling: Mounting E

Ta (°C)	Load (%)
-20 - +36	100
60	40
70	15



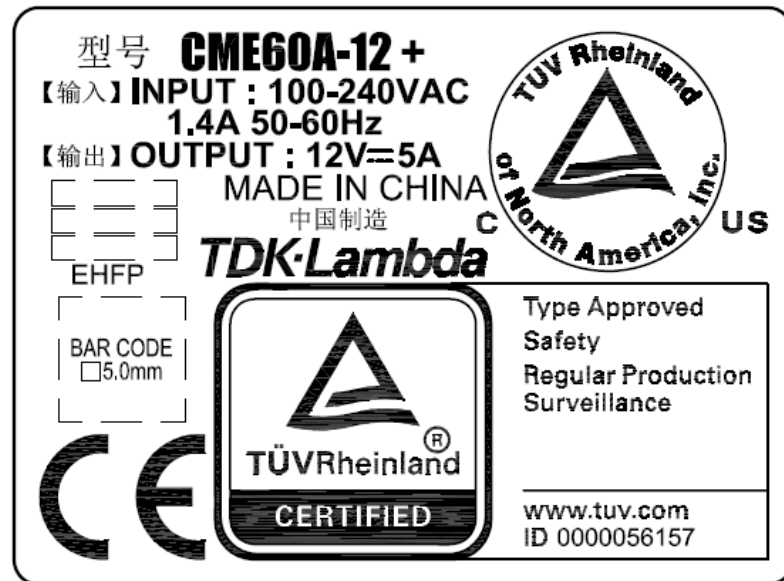
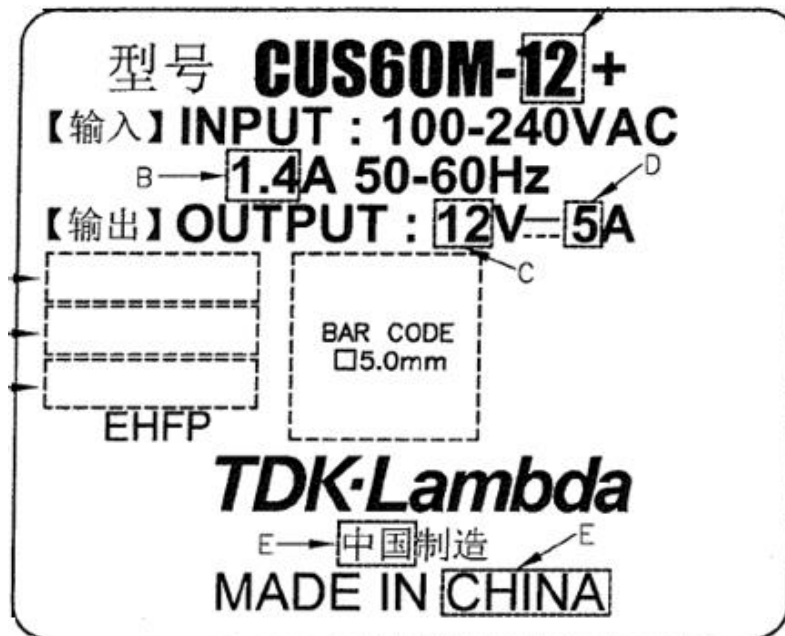
The equipment is operated up to 5000m above sea level as declared by manufacturer. Clearances have been evaluated according to IEC 60601-1 table 8 with a multiplication factor of 1.29 throughout this report.

Tests performed (name of test and test clause):	Testing location:
<ul style="list-style-type: none"> <li>• 4.11 Power input</li> <li>• 5.7 Humidity pre-conditioning</li> <li>• 7.1.3 Marking durability</li> <li>• 8.4.2 ACCESSIBLE PARTS and APPLIED PARTS</li> <li>• 8.4.3 Discharge</li> <li>• 8.5.4 Working voltage</li> <li>• 8.6.4 Impedance and current-carrying capability</li> <li>• 8.7.4 Leakage currents</li> <li>• 8.8.3 Dielectric strength</li> <li>• 8.8.4.1 Ball-pressure test</li> <li>• 11.1 Excessive temperatures</li> <li>• 13 Hazardous situations and fault conditions</li> <li>• 15.5 Mains supply transformers and transformers providing safety isolation</li> </ul>	<p>TÜV Rheinland Shanghai Co., Ltd. No.177, 178, Lane 777 West Guangzhong Road, Jing'an District, Shanghai, China</p>
<p><b>Summary of compliance with National Differences</b></p> <p>List of countries addressed: AR, AU, AT, BH, BY, BE, BR, BG, CA, CN, CO, HR, CZ, DK, FI, FR, DE, GR, HU, IN, ID, IE, IL, IT, JP, KE, KR, LR, MY, MX, AN, NZ, NG, NO, PK, PL, PT, RU, SA, RS, SG, SK, SI, ZA, ES, SE, CH, TH, TR, UA, AE, GB, US, VN</p> <p>Explanation of used codes: AR = Argentina*; AU = Australia*; AT = Austria*; BH = Bahrain*; BY = Belarus*; BE = Belgium*; BR = Brazil*; BG = Bulgaria*; CA = Canada**; CN = China*; CO = Colombia*; HR = Croatia*; CZ = Czech Republic*; DK = Denmark*; FI = Finland*; FR = France*; DE = Germany*; GR = Greece*; HU = Hungary*; IN = India*; ID = Indonesia*; IE = Ireland*; IL = Israel*; IT = Italy*; JP = Japan*; KE = Kenya*; KR = Korea, Republic Of; LR = Libya*; MY = Malaysia*; MX = Mexico*; AN = Netherlands Antilles*; NZ = New Zealand*; NG = Nigeria*; NO = Norway*; PK = Pakistan*; PL = Poland*; PT = Portugal*; RU = Russian Federation*; RO = Romania*; SA = Saudi Arabia*; RS = Serbia, Republic of*; SG = Singapore*; SK = Slovakia*; SI = Slovenia*; ZA = South Africa*; ES = Spain*; SE = Sweden; CH = Switzerland*; TH = Thailand*; TR = Turkey*; UA = Ukraine*; AE = United Arab Emirates*; GB = United Kingdom; US = United States of America*; VN = Vietnam*</p> <p>Note(s): Countries outside the CB Scheme membership may also accept this report. * No National Differences Declared ** National differences to IEC 60601-1:2005 evaluated</p> <p><b>The product fulfils the requirements of</b> EN 60601-1:2006+A11:2011+A1:2013+A12:2014 ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1 CAN/CSA-C22.2 NO. 60601-1:14 CAN/CSA-C22.2 NO. 60601-1-08 (R2013)</p>	

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.

<Representative>



Remark: The rating labels of all models have the same design except for the model designation and output ratings.

<b>GENERAL INFORMATION</b>	
<b>Test item particulars (see also Clause 6):</b>	For not classified ME equipment and a built-in, open frame type switching mode power supply
Classification of installation and use .....	Fixed
Device type (component/sub-assembly/ equipment/ system):	Sub-assembly
Intended use (Including type of patient, application location) :	By other methods validated described by the manufacturer
Mode of operation .....	Continuous
Supply connection .....	Primary connector
Accessories and detachable parts included .....	None
Other options include .....	None
<b>Testing</b>	
Date of receipt of test item(s) .....	2017-05-22
Dates tests performed .....	2017-05-27 to 2017-06-30
<b>Possible test case verdicts:</b>	
- 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 (collateral standards only)
- test object does not meet the requirement.....	Fail (F)
<b>Abbreviations used in the report:</b>	
- normal condition .....	N.C.
- single fault condition .....	S.F.C.
- means of Operator protection .....	MOOP
- means of Patient protection .....	MOPP
<b>General remarks:</b>	
<p>"(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.  <b>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</b>            This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3<sup>rd</sup> edition + AM1.            The Risk Management was excluded from the investigation; this shall be clearly identified in this report and on the accompanying CB Test Certificate.            Additional test data and/or information may be provided in the attachments to this report.</p>	

Manufacturer's Declaration per sub-clause 4.2.5 of IEC60061:2012						
<p>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.....:</p> <p>When differences exist; they shall be identified in the General product information section.</p>						
<p>Name and address of factory (ies)..... :</p> <ol style="list-style-type: none"> <li>1. Wuxi TDK-Lambda Electronics Co., Ltd. No. 6 Xing Chuang Er Lu 214028, Wuxi, Jiangsu China</li> <li>2. Zhangjiagang Hua Yang Electronics Co., Ltd. Zhao Feng Industrial Zone, Leyu Town, 215622 Zhangjiagang, Jiangsu, P. R. China</li> <li>3. Sendan Electronics Mfg. Co., Ltd. 1010 Habushin Nanto-shi, Toyama 939-1756 JAPAN</li> <li>4. ALPS Logistics Facilities Co., Ltd. 593-1 Nishi-Ohashi, Tsukuba-shi, Ibaraki, 305-0831, JAPAN</li> <li>5. TDK-Lambda Corp. Nagaoka Technical Center 2704-1 Settaya-machi, Nagaoka-shi, Niigata 940-1195, JAPAN</li> </ol>						
<p><b>General product information:</b></p> <p>The PSU is a component type switching mode power supplies intended for the earthed construction or non-earthed construction of medical equipment.</p> <ul style="list-style-type: none"> <li>- For earthed construction (Class I), the PSU need to be reliably earthed and professionally installed and fixed with metal screws.</li> <li>- For non-earthed construction (Class II), no earthing connection is required. The PSU need to be fixed so, that it is insulated from any unearthed accessible conductive part by reinforced insulation.</li> </ul> <p>Model CME60A-zzxxxxxxx is identical to model CUS60M-zzxxxxxxx except for model name.</p> <p>All models are identical, except of the optional chassis, cover, turns of Transformer and the rating of some components which results in different output ratings. See Model List below for details.</p> <p><b>For rating differences between the models see below tables:</b></p>						
Series Model	I/p voltage (Vac)	Freq (Hz)	I/p current (A)	Minimal output	Rated output (typical)	Maximum output
CUS60M-5 xxxxxxxx CME60A-5 xxxxxxxx	100-240	50-60	1.0	4.85Vdc	5Vdc	5.15Vdc
				6A	6A	5.83A
CUS60M-12 xxxxxxxx CME60A-12 xxxxxxxx	100-240	50-60	1.4	11.7Vdc	12Vdc	12.3Vdc
				5A	5A	4.88A
CUS60M-15 xxxxxxxx CME60A-15 xxxxxxxx	100-240	50-60	1.4	14.625Vdc	15Vdc	15.375Vdc
				4A	4A	3.9A
CUS60M-18 xxxxxxxx CME60A-18 xxxxxxxx	100-240	50-60	1.4	17.55Vdc	18Vdc	18.45Vdc
				3.35A	3.35A	3.27A



CUS60M-24 xxxxxxxx CME60A-24 xxxxxxxx	100-240	50-60	1.4	23.4Vdc	24Vdc	24.6Vdc
				2.5A	2.5A	2.44A
CUS60M-36 xxxxxxxx CME60A-36 xxxxxxxx	100-240	50-60	1.4	35.1Vdc	36Vdc	36.9Vdc
				1.68A	1.68A	1.64A
CUS60M-48 xxxxxxxx CME60A-48 xxxxxxxx	100-240	50-60	1.4	46.8Vdc	48Vdc	49.2Vdc
				1.25A	1.25A	1.22A
CUS60M-5/ADJ CME60A-5/ADJ	100-240	50-60	1.4	4.5Vdc	5Vdc	5.5Vdc
				6A	6A	5.45A
CUS60M-12/ADJ CME60A-12/ADJ	100-240	50-60	1.4	10.8Vdc	12Vdc	13.2Vdc
				5A	5A	4.55A
CUS60M-15/ADJ CME60A-15/ADJ	100-240	50-60	1.4	13.5Vdc	15Vdc	16.5Vdc
				4A	4A	3.64A
CUS60M-18/ADJ CME60A-18ADJ	100-240	50-60	1.4	16.2Vdc	18Vdc	19.8Vdc
				3.35A	3.35A	3.05A
CUS60M-24/ADJ CME60A-24/ADJ	100-240	50-60	1.4	21.6Vdc	24Vdc	26.4Vdc
				2.5A	2.5A	2.27A
CUS60M-36/ADJ CME60A-36/ADJ	100-240	50-60	1.4	32.4Vdc	36Vdc	39.6Vdc
				1.68A	1.68A	1.53A
CUS60M-48/ADJ CME60A-48/ADJ	100-240	50-60	1.4	43.2Vdc	48Vdc	52.8Vdc
				1.25A	1.25A	1.14A
Remark: Operating temp.: up to +70°C (operating temperature depending on equipment's load, mounting position, for details refer to instruction manual).						

#### Additional Information

- This PSU subject to this evaluation is not a medical device or system on its own right, but a component intended for building into such. Risk assessment was therefore not subject of this investigation. It shall be carried out for final medical electrical equipment or system.
- The insulation system of the PSU was evaluated for compliance with the **MEANS OF PATIENT PROTECTION (MOPP)**.
- Compliance with IEC / EN 60601-1-2 shall be evaluated during the end system evaluation.
- The product is for building-in equipment, the overall compliance shall be investigated in the complete medical electrical equipment or system, in particular:
  - Fire enclosure
  - Mechanical enclosure
  - Electrical enclosure
- Some components are **pre-certified**, which have been evaluated according to the relevant requirements of IEC 60601-1, are employed in this product.
- The equipment does not have circuits for direct connection to the patient and not is intended for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.
- The input circuit includes one fuse (F1A) in the Line conductor and the other fuse (F1B) is optional in

neutral conductor. Consideration shall be given in the end-use product regarding addition of the second fuse having the same or better characteristics in order to comply with fusing requirements of Clause 8.11.5 of the standard.

Note:

PSU = Power Supply Unit

**Definition of variable(s):**

CUS60M-zzxxxxxxx; CME60A-zzxxxxxxx (zz = 5,12,15,18,24,36 or 48; xxxxxxx = A, U, ADJ, M, CO, SF, other alphanumeric character)

Note: Suffix options would be used shown below or used together.

Variable:	Range of variable:	Content:
zz	5, 12, 15, 18, 24, 36 or 48	Denotes for output voltage
xxxxxxx	/A	Denotes for chassis & cover
	/U	Denotes for U shape chassis
	/ADJ	Denotes for output adjust
	/M	Denotes for Molex connector
	/CO	Denotes for PWB coating
	/SF	Denotes for single fuse
	other alphanumeric character	For market purposes, no construction differences and no safety impact.

1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:

- Clause 7.2.7 ELECTRICAL INPUT POWER FROM THE SUPPLY MINS,
- Clause 7.5 SAFETY SIGNS,
- Clause 7.6 SYMBOLS,
- Clause 7.9 ACCOMPANYING DOCUMENTS,
- Clause 9 PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS,
- Clause 10 PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS,
- Clause 12 ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS,
- Clause 14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS),
- Clause 16 ME SYSTEMS,
- Risk Management was excluded from this investigation

2. Risk Controls/ Engineering Considerations for component power supply:

For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the following:

- For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.

- For Power Supplies with No RM: End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1).
- For Power Supplies with No RM: End product Risk Management Process to consider the need for simultaneous fault condition testing.
- For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.
- For Power Supplies with No RM with Exposure Condition outside of Humidity Range: Power Supply tested in 40°C, 95%RH. End product Risk Management Process to determine risk acceptability criteria.
- For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- For Power Supplies with No RM and Not tested with Test Corner: Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.
- For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- For Power Supplies with No RM or Units with Liquids: End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- For Power Supplies with No RM or Units with Indicators: End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
- For Power Supplies with No RM or Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply
- For Power Supplies with Thermal Cut-off and No RM: End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply
- For Power Supplies with Pre-set components and No RM: End product to determine the acceptability of risk in conjunction to the use of Pre-set controls as part of the power supply.