Test Report issued under the responsibility of:

TÜVRheinland®

TEST REPORT
IEC 60601-1
Part 1: General requirements for basic safety and essential performance

Report Number. .....:	15077101 001
Date of issue .....:	2015-06-09
Total number of pages.....:	124
Name of Testing Laboratory preparing the Report.....:	TÜV Rheinland (Shanghai) Co., Ltd. B1-13/F, No.177, Lane 777, West Guangzhong Road, Zhabei District, Shanghai 200072, P. R. China
Applicant's name.....:	TDK-Lambda Corp. Nagaoka Technical Center
Address .....:	2704-1 Settaya-machi, Nagaoka-shi, NIIGATA 940-1195, JAPAN
Test specification:	
Standard .....:	IEC 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1 (2012 reprint)
Test procedure.....:	CB Scheme
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_1J_PS
Test Report Form(s) Originator.....:	UL(US)
Master TRF .....:	2014-09

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.

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 ..... :	**TDK·Lambda**
Manufacturer ..... :	Same as applicant
Model/Type reference ..... :	CUS350M-**zxxxxxxx** (**z** = 12, 18, 24 or 48; **xxxxxxx** = F, PG, 2, F2, PG2, S**, 0-9, a-z, A-Z, other alphanumeric character, symbol or blank) Refer to page 8 for definition of variables
Ratings ..... :	AC input: 100-240V, 4.0A, 50-60Hz DC output: See the model list on page 7 for details

Testing procedure and testing location:		
☒ **CB Testing Laboratory:**	TÜV Rheinland (Shanghai) Co., Ltd.	
Testing location/ address ..... :	B1-13/F, No.177, Lane 777, West Guangzhong Road, Zhabei District, Shanghai 200072, P. R. China	
☐ **Associated CB Testing Laboratory:**		
Testing location/ address ..... :		
Tested by (name + signature) ..... :	Angela Lee	
Approved by (name + signature) ..... :	Mark Chen	
☐ **Testing procedure: TMP/CTF Stage 1:**		
Testing location/ address ..... :		
Tested by (name + signature) ..... :		
Approved by (name + signature) ..... :		
☐ **Testing procedure: WMT/CTF Stage 2:**		
Testing location/ address ..... :		
Tested by (name + signature) ..... :		
Witnessed by (name + signature) ..... :		
Approved by (name + signature) ..... :		
☐ **Testing procedure: SMT/CTF Stage 3 or 4:**		
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 - Technical Documentation (52 pages)
- Attachment 2 - Photo Documentation (22 pages)
- Attachment 3 - National Difference (8 pages)

Summary of testing:

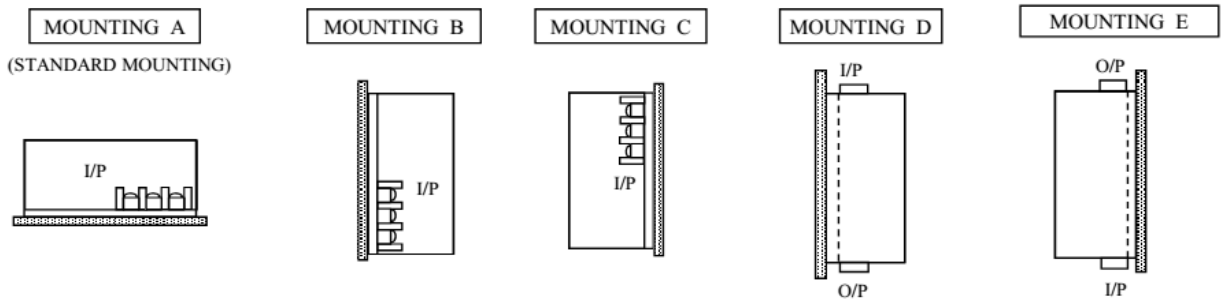
All applicable tests as described in Test Case and Measurement Sections were performed.

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 according to sub-clause 1.2.2.1 for this equipment is the operation with the maximum specified DC-load with maximum power condition according to the manufacturer specified.

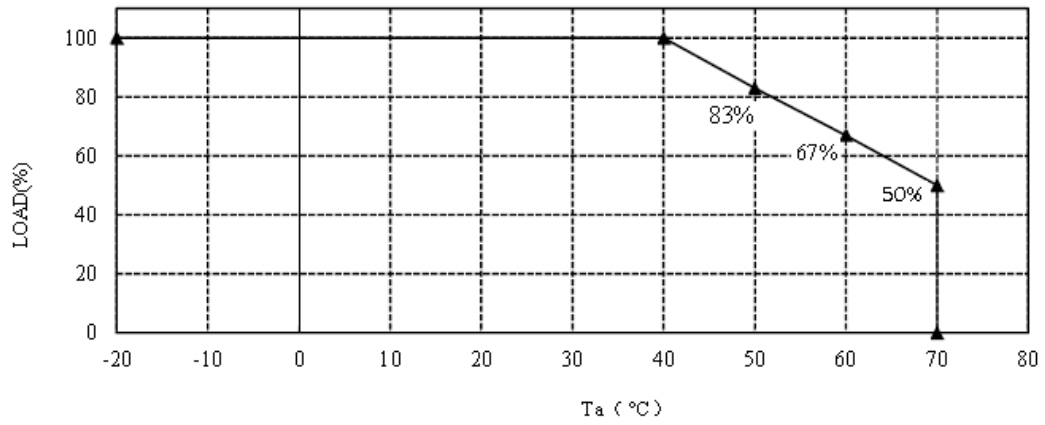
Mounting position:



De-rating Curve:

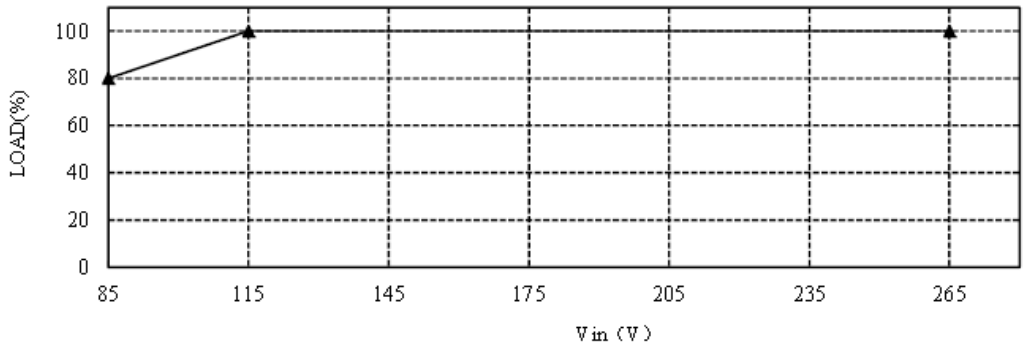
OUTPUT DERATING VERSUS OPERATING AMBIENT TEMPERATURE (Ta)

Ta (°C)	LOAD (%)
-20 - +40	100
50	83
60	67
70	50



OUTPUT DERATING VERSUS INPUT VOLTAGE

INPUT VOLTAGE (VAC)	LOAD (%)
85	80
115~265	100



The equipment is operated up to 4000m above sea level as declared by manufacturer. Clearances have been evaluated according to IEC 60601-1 table 8 with a multiplication factor of 1.14 throughout this report.

Tests performed (name of test and test clause):	**Testing location:**
• 4.11 Power input • 5.7 Humidity pre-conditioning • 7.1.3 Marking durability • 8.4.2 ACCESSIBLE PARTS and APPLIED PARTS • 8.4.3 Discharge • 8.5.4 Working voltage • 8.6.4 Impedance and current-carrying capability • 8.7.4 Leakage currents • 8.8.3 Dielectric strength • 8.8.4.1 Ball-pressure test • 11.1 Excessive temperatures • 13 Hazardous situations and fault conditions • 15.5 Mains supply transformers and transformers providing safety isolation	TÜV Rheinland (Shanghai) Co., Ltd. B1-13/F, No.177, Lane 777, West Guangzhong Road, Zhabei District, Shanghai 200072, P. R. China

Summary of compliance with National Differences

List of countries addressed:

AT, CA, GB, KR, SE, US

Explanation of used codes:

AT=Austria; CA=Canada; GB=United Kingdom; KR=Korea of Republic; SE=Sweden; US = United States of America.

The product fulfils the requirements of

EN 60601-1:2006++A11:2011+A1:2013+A12:2014

ANSI/AAMI ES60601-1:2005+A2 (R2012) +A1

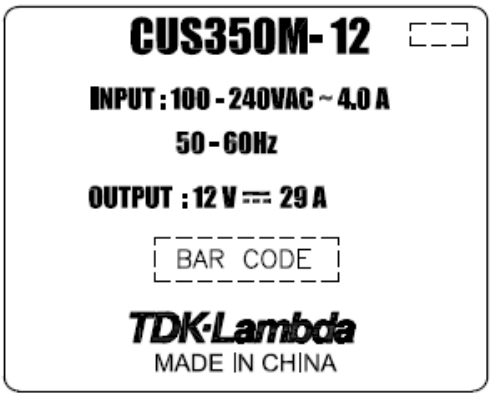
CAN/CSA-C22.2 NO. 60601-1:14

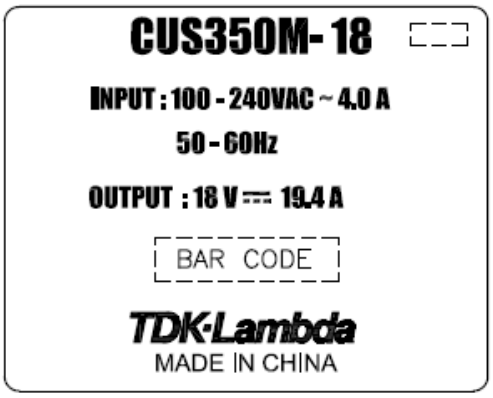
CAN/CSA-C22.2 NO. 60601-1-08 (R2013)

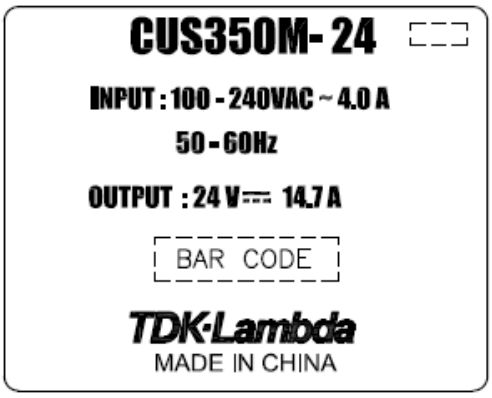
Copy of marking plate

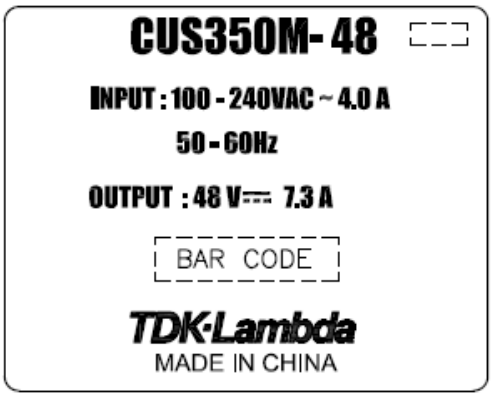
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

<Representative>









GENERAL INFORMATION	
Test item particulars (see also Clause 6):	For Class I 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 ..... :	Altitude during operation: up to 4000m IP protection class: IPX0 Mass of equipment: approx. 0.8 kg
Testing	
Date of receipt of test item(s) ..... :	2015-03-08
Dates tests performed ..... :	2015-03-09 to 2015-04-13
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 (collateral standards only)
- 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.

This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3rd 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.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012

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)..... :

1. Wuxi TDK-Lambda Electronics Co., Ltd. No. 6 Xing Chuang Er Lu, 214028 Wuxi, Jiangsu, China
2. Zhangjiagang Hua Yang Electronics Co., Ltd. Zhao Feng Industrial Zone, Leyu Town, 215622 Zhangjiagang, Jiangsu, China

General product information:

The EUT is a component type switching mode power supplies intended for the class I construction of information technology equipment.

All models are identical, except of the turns of Transformer and the rating of some components which results in different output ratings. See Model List below for details.

For rating differences between the models see below tables:

Series Model	I/p voltage (Vac)	Freq (Hz)	I/p current (A)	Minimal output	Rated output (typical)	Maximum output
CUS350M-12**xxxxxxx**	100-240	50-60	4.0	11.4 Vd.c.	12 Vd.c.	12.6 Vd.c.
				29 A	29 A	27.6 A
CUS350M-18**xxxxxxx**	100-240	50-60	4.0	17.1 Vd.c.	18 Vd.c.	18.9 Vd.c.
				19.4 A	19.4 A	18.5 A
CUS350M-24**xxxxxxx**	100-240	50-60	4.0	22.8 Vd.c.	24 Vd.c.	25.2 Vd.c.
				14.7 A	14.7 A	14 A
CUS350M-48**xxxxxxx**	100-240	50-60	4.0	45.6 Vd.c.	48 Vd.c.	50.4 Vd.c.
				7.3 A	7.3 A	7.0 A
Remark: Operating temp.: up to +70ºC (operating temperature depending on equipment's load and operation ambient temperature 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.

Note:
PSU = Power Supply Unit

Definition of variable(s):

CUS350M-**zxxxxxxx**
(**z** = 12, 18, 24 or 48; **xxxxxxx** = F, FN,PG, 2, F2, PG2, S**, 0-9, a-z, A-Z, other alphanumeric character, symbol or blank)

Variable:	Range of variable:	Content:
z	12, 18, 24 or 48	Denotes for different output voltage
xxxxxxx	blank	Denotes for Standard type
	F	Denotes for Full function
	FN	Denotes for Fan Power Terminal
	PG	Denotes for power good
	2	Denotes for PWB coating
	F2	Denotes for full function and PWB coating
	PG2	Denotes for power good and PWB coating
	S**	Denotes for special modified model, not affect safety
	0-9, a-z, A-Z, other alphanumeric character, symbol or blank	Denotes 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.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

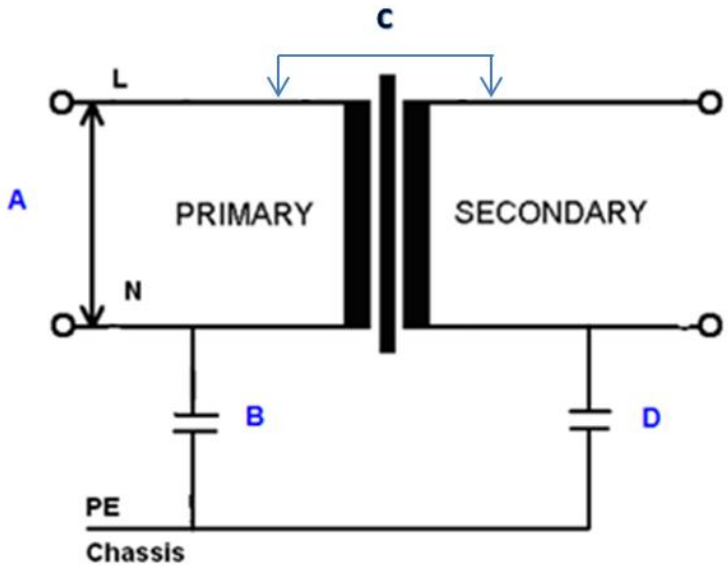


TABLE: INSULATION DIAGRAM		Pass
Pollution degree ..... :	2	—
Overvoltage category..... :	II	—
Altitude..... :	4000	—
Additional details on parts considered as applied parts ..... :	☒ **None** ☐ **Areas** _____ **(See Clause 4.6 for details)**	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V_{rms}	V_{pk}					
A	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	5.0	5.0	Primary traces before fuse
--	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	4.5	4.5	Primary traces under fuse F1
--	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	4.5	4.5	Primary traces under fuse F2
B	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	5.9	3.8	N to PB (with slot 8.5x1.5mm)

IEC 60601-1									
Clause	Requirement + Test					Result - Remark			Verdict
B	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	7.5	7.5	Under C2
B	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	6.7	3.5	Under C3 (with slot 8.5x1.5mm)
B	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	7.8	7.8	Under C6
B	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	6.5	6.5	BD1 to HS1
B	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	7.2	7.2	SC1A, SC1B, Q2A, Q2B to HS1
B	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	9.5	4.7	L4 core to HS1
B	1MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	6.0	6.0	C6 primary to HS2
C	2MOPP	IIIb	<400	<566	12	8.0 (7x1.14)	15.0	15.0	Under T1
C	2MOPP	IIIb	<400	<566	12	8.0 (7x1.14)	25.6	25.6	Under T2
C	2MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	8.3	8.3	Under PC101
C	2MOPP	IIIb	<250	<354	4	2.9 (2.5x1.14)	8.3	8.3	Under PC102

Supplementary Information:

1. For clearance and creepage did not describe as above are far larger than limit.
2. Construction details for transformer: **Refer to attachment 1 – Technical documentation**
3. For all models

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.