Underwriters Laboratories (UL LLC)
Safety Certification Body (CB) Report

Model:	Series : Alpha 400, Alpha 400W, CA400, MA400, Alpha-400, Alpha-400W; models : CA400, CA-400, MA400, MA-400
Device Description:	Switch Mode Power Supply
Applicant:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Manufacturer:	Same as Applicant
Manufacturing Facility(ies):	Same as Applicant Panyu Trio Microtronics Co Ltd SHIJI INDUSTRIAL ESTATE DONGYONG NANSHA GUANGZHOU GUANGDONG 511453 CN
Report No.:	E349607-D1028-1/A1/C0-CB
Report (Re)Issue Date:	2023-12-13; A1: 2024-03-13
Base Standard(s):	IEC 60601-1:2005, AMD1:2012, AMD2:2020
Additional Standards:	-
Report Types:	This report consists of the following report types: - CB Report & Certificate

This report covers the Safety evaluation of the referenced model(s) according to the standard(s) specified above.

The **CB Certificate** is provided as a separate enclosure to this report and not provided in the body of this report.

Table of Contents

REPORT CONTENTS: 1
Test Report 1
TABLE: List of critical components 202
APPENDIX A: Enclosures *(Page Section: A)* 1
Collateral/Particular Standard Enclosures 1
Other Enclosures 2
Diagrams - (001) 4-01 Primary Assy 3
Diagrams - (002) 4-02 1 Turn Secondary Assy 4
Diagrams - (003) 4-03 2 Turn Secondary Assy 5
Diagrams - (004) 4-04 3 Turn Secondary Assy 6
Diagrams - (005) 4-05 4 Turn Secondary Assy 7
Diagrams - (006) 4-06 Flyback Transformer Assy 8
Diagrams - (007) 4-07 Flyback Transformer Assy - Alternate 9
Licenses - (001) 8-01 Licenses 10
Licenses - (002) 8-03 Xiamen 84
Manuals - (001) 6-01 Manual(s) 85
Marking Label - (001) MarkingPlate 111
Miscellaneous - (001) 7-01 Marking Plate 112
Miscellaneous - (002) 7-02 Products Covered 113
Miscellaneous - (003) 7-03 Declaration of Product Equivalence for the Manufacturin 116
Miscellaneous - (004) 7-04 CB Test Certificate Information 117
Miscellaneous - (005) jp_nd_iec60601_1u_2023-08-22 119
Photographs - (001) 3-02 External View 131
Photographs - (002) 3-03 Filter Assy 132
Photographs - (003) 3-04 Output Module 133
Photographs - (004) 3-05 Unit with Cover Removed 134
Photographs - (005) 3-06 Converter Assy 135
Photographs - (006) 3-07 Options 136
Schematics + PWB - (001) 5-01 Converter 137
Schematics + PWB - (002) 5-02 Filter 138
Schematics + PWB - (003) 5-03 Forward Converter 139
Schematics + PWB - (004) 5-04 Boost Converter 140
Schematics + PWB - (005) 5-05 Single Module 141
Schematics + PWB - (006) 5-06 Twin Module 142
Schematics + PWB - (007) 5-07 Dual Module 143
TEST RESULTS: 1
APPENDIX B: Test Datasheets Enclosures (Page *Section: B)* 1
National Differences 1

Report Modifications Summary

The following changes were made to this report. If none listed in the below table, this report is the originally issued report.

The following scheme is used throughout this report to reflect the **Report No.**:

(File No.) – (Report Ref. No.) – (x) / A(y) / C(z) – YYY, where:
(x) = Report (Re)Issue No.
(y) = Amendment No.
(z) = Correction No.
YYY = Report Type (UL/CB/IEC)

*NOTE: The **CB Certificate** may not be updated for report corrections that don't affect the CB Certificate contents; therefore if this report includes a correction number (z), it may not be reflected in the CB Certificate.*

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2023-12-13	Unless otherwise indicated, all tests were conducted at TDK-Lambda Ltd., Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United Kingdom. Report was issued based on E349607-D7-CB-2 (issued: 2015-06-01) test report, test certificate no. DK-45831-M1-UL. No testing was considered necessary to meet the requirements of AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14, IEC 60601-1:2005, AMD1:2012, AMD2:2020 based on standard similarity. Following changes were introduced in comparison to E349607-D7-CB-2 (issued: 2015-06-01) test report: - addition of following components to list of critical components: alternatives for L4 earth choke, alternatives for C4, C5, C6, C7 Y capacitors, alternatives for C1, C2, C3 X capacitors, Core used in T205 (previously not exicitng on the list) - revisions of standards and certificates numbers on the list of critical components, - addition of national differences for Japan. No testing was considered necessary to introduce above mentioned changes.	Krzysztof Wasilewski
2024-03-13	This is a technical amendment to the report E349607-D1028-1/A0/C0 to add an alternate L101 choke bobbin material. See Critical components table. After review of construction and documentation the device continues to comply with the requirements. No testing was considered necessary to introduce above mentioned changes.	Jakub Szymański

Test Report issued under the responsibility of:

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Number. .....:	E349607-D1028-1/A1/C0-CB
Date of issue .....:	2023-12-13; A1: 2024-03-13
Total number of pages.....:	210
Name of Testing Laboratory preparing the Report.....:	UL International Polska Sp. z o.o. Równoległa 4 PL-02-235 Warszawa POLAND
Applicant's name.....:	TDK-LAMBDA UK LTD
Address .....:	KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Test specification:	
Standard.....:	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure .....:	CB Scheme
Non-standard test method……..:	N/A
TRF template used. .....:	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No.....:	IEC60601_1U
Test Report Form(s) Originator ....:	UL(US)
Master TRF .....:	2023-08-24

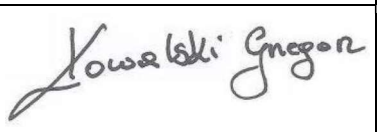
If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved IECEE 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 NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description.....:	Switch Mode Power Supply
Trade Mark(s) .....:	TDK·Lambda
Manufacturer .....:	Same as Applicant
Model/Type reference.....:	Series : Alpha 400, Alpha 400W, CA400, MA400, Alpha-400, Alpha-400W; models : CA400, CA-400, MA400, MA-400
Ratings.....:	Nominal input voltage range: 100 – 240Vac, 7A max, 47-63Hz Output: See Model Differences (see model differences for details of model ratings)

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
[X]	**CB Testing Laboratory:**		
Testing location/ address ..... :		UL International Polska Sp. z o.o. Równoległa 4 PL-02-235 Warszawa POLAND	
Tested by (name, function, signature) ..... :		Jakub Szymański (handler)	
Approved by (name, function, signature) .. :		Grzegorz Kowalski (reviewer)	
[ ]	**Testing procedure: CTF Stage 1:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Approved by (name, function, signature) .. :			
[ ]	**Testing procedure: CTF Stage 2:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) . :			
Approved by (name, function, signature) .. :			
[X]	**Testing procedure: CTF Stage 3:**		

[ ]	**Testing procedure: CTF Stage 4:**		
Testing location/ address ..... :		TDK-Lambda UK Ltd, Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United Kingdom	
Tested by (name, function, signature) ..... :		T. Burgess S. Hirstwood	See the original CBTR for signature
Witnessed by (name, function, signature) . :		-	
Approved by (name, function, signature) .. :		K.P. Tizzard	See the original CBTR for signature
Supervised by (name, function, signature) :		Krzysztof Wasilewski	See the original CBTR for signature

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

Refer to Appendix A of this report. All attachments are included within this report.

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
Refer to the Test List in Appendix B of this report if testing was performed as part of this evaluation.	*Refer to the Test List in Appendix B of this report if testing was performed as part of this evaluation.*

Summary of compliance with National Differences (List of countries addressed):

List of countries addressed: United States of America, Canada, Japan

[X] The product fulfils the requirements of National standard AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14, National standard JIS T 0601-1:2023.

Statement concerning the uncertainty of the measurement systems used for the tests
(may be required by the product standard or client)

[ ] **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**
Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

[X] **Statement not required by the standard used for type testing**
(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

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.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

Test item particulars ..... :	
Classification of Installation and Use:	For building-in
Supply Connection:	For building-in
Device type (component/sub-assembly/ equipment/ system):	Component Power Supply
Intended use (Including type of patient, application location):	for building-in MD and to supply regulated power
Mode of Operation:	Continuous
Accessories and detachable parts included:	None
Other Options Include:	None
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement .....:	P (Pass)
- test object was not evaluated for the requirement..... :	N/E (collateral standards only)
- test object does not meet the requirement .....:	F (Fail)
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
Testing.....:	
Date of receipt of test item .....:	2004-11-05, 2011-03-02, 2012-05-04, 2012-05-11
Date(s) of performance of tests .....:	2004-11-05, 2012-05-04 to 2012-05-16

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 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

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies)..... :	Same as Applicant Panyu Trio Microtronics Co Ltd SHIJI INDUSTRIAL ESTATE DONGYONG NANSHA GUANGZHOU GUANGDONG 511453 CN

General product information and other remarks:

Report Summary

See report modifications table

Refer to the Report Modifications for any modifications made to this report.

Product Description

Products are component AC/DC Switching Mode Power Supplies intended to be used as part of Medical Electrical Equipment

Model Differences

The Alpha 400, CA 400 and MA 400 Series Power Supplies are electrically and mechanically identical.
The system build is further specified by additional suffixes, described as follows:
may be followed by A, LL, RL, ML and TL, or no letter; where
A = Class A input filter
TL = Tiny Leakage Input Filter
RL = Reduced Leakage Input filter
LL = Low Leakage Input filter
ML = Medium Leakage Filter
No letter = Class B input filter
may be followed by LSF, QF or RA; where
LSF = Low Speed Fan
QF = Quiet Fan
RA = Reverse Air Flow Fan is fitted
followed by up to five of the following:
@ followed by AA, A, AL, BB, B, CC, C, CL, CM, CH, DD, D, FF, F, GG, G, JJ, J, KK, K, LL, L, MM, M, NN, N, QQ, Q, RR, R, SS, S, TT, T, UU, U, WW, W, ZZ or Z.
or B/S
optionally followed by: _X, _MF, MFE, MFU, MFV or _MFV, MFPF, _PA, _IN, _PP, MJ, RJ, PJ, IJ, _RP, RPA, RPB, RPC, RPD, _MG, _D
@/@ or @_@ followed by: E, EB, EQ, EL, EH, H, P or PL:
where @ and @/@ or @_@ = applicable voltage range and the following one or two letters are the module type
_MF, MFE = Mains fail option (may also be called X)
MFU = Mains fail option with uncommitted output connections
MFV or _MFV = Mains fail option with VME bus
_PA, _PP, _IN, _RP = Secondary module options
B/S = blanking slot which occupies one 23 mm slot.
MFPF = Mains fail, module parallel, PSU/fan inhibit and 5V, 50mA auxiliary output
MJ = Mains fail option
Only up to five 23 mm slots may be filled up per unit, noting that all modules occupy one 23 mm slot except for AA, A, F, G, J, K, R, S and T modules which occupy two 23 mm slots. All primary MF options can only be fitted in slot 1.
Valid voltage ranges for @ and @/@ or @_@ for each module are as follows:
Module Voltage Range
A @ = 4.5 - 6V
AA @ = 4.5 - 7V
AL @ = 4.75 - 5.3V
BB @ = 4.5 - 7V
B @ = 4.5 - 6V
C, CC @ = 5 - 16V
CL @ = 4.6 - 5.6V
CM @ = 5 - 7V
CH @ = 11.4 - 13.5V
D, DD @ = 18 - 29V
E @/@ or @_@ = 5 - 16V / 5 - 16V
EL @/@ or @_@ = 5 - 7V / 11 - 13V

EH @/@ or @_@ = 11 - 13V / 11 - 13V
EB @/@ or @_@ = 4.5 - 5.5V / 4.5 - 5.5V
EQ @/@ or @_@ = 4.5 - 5.5V / 2.7 - 3.9V
F @ = 9 - 16V
G, GG @ = 17.5 - 29V
H @/@ or @_@ = 18 - 32V / 18 - 32V
J, JJ @ = 30 - 48V
K, KK @ = 18 - 31V
L, LL @ = 1.8 - 3.2V
M, MM @ = 5 - 16V
N, NN @ = 18 - 32V
P @/@ or @_@ = 18 - 29V / 5 - 16V
PL @/@ or @_@ = 22 - 26V / 5 - 7V
Q, QQ @ = 2.7 - 3.9V
R, RR @ = 2.7 - 3.9V
S, SS @ = 1 - 5.7V
T, TT @ 1.8V - 3.2V
U, UU @ 10 - 21V
W, WW @ 4.5 - 5.5V
Z, ZZ @ 4.5 - 5.7V
Secondary Options:
Option Description
_MG Provides a module good signal which indicates output voltage is within limits
_PA, RJ Forces paralleled modules to share load current. Additionally it also provides the module good signal
_PP, PJ Provides either of the following functions:
a) Reduces module current limit and caters for paralleled modules with bus bar linking. For use with modules providing a max output of up to 16V only; or
b) Identical to _PA except that the module is paralleled at the output of the module with bus bar linking
_IN, IJ Provides an external signal which may be used to inhibit the output of the module
_RP Provides remote programming of the module output voltage
RPA Provides voltage programming of the module output voltage only
RPB Provides voltage programming of the module output voltage and has an output VA limiting circuit
RPC Provides an output VA limiting circuit
RPD Provides voltage programming of the module output voltage and has an output VA limiting circuit
_D Provides a delay to the turn on time of the output
Note:
The RPA option can only be used on modules with output voltages rated up to 32V
The RP, RPB, RPC and RPD options can only be used on modules with output voltages rated up to 16V. Not for use with a module voltage range of 18-29V or twin output modules.
a) A, AA & AL modules can be used in slots 1-5 up to 60A/channel
b) BB & B modules can be used in slots 1-4 up to 25A/channel and in slot 5 up to 20A/channel
c) C, CC, CL, CM & CH modules can be used in slots 1-5 up to 16A/channel if o/p is limited to 12V. At 15 to 16V C modules can be used up to 12A/channel. Module derates linearly between 12 and 15V
d) D & DD modules can be used in slots 1-5 up to 8A/channel
e) E, EL & EH modules can be used in slots 1-3 up to 8A/channel and in slots 4 and 5 up to 6A/channel
f) EB modules can be used in slots 1-5 up to 9A/channel
g) EQ modules can be used in slots 1-3 up to 9A/channel and in slots 4 and 5 up to 6.75A/channel
h) F & FF modules can be used in slots 1-5 up to 33A/channel
i) G & GG modules can be used in slots 1-5 up to 20A/channel
j) H modules can be used in slots 1-3 up to 5A/channel and in slots 4 and 5 up to 4A/channel. For output voltages 30.01 to 32V maximum rated current is 1A
k) J & JJ modules can be used in slots 1-5 at 30-41V at 10A max. For output of 48V at 8A max. For voltages between 41 and 48V the current is linearly interpolated
l) K & KK modules can be used in slots 1-5 up to 15A
m) M & MM modules can be used in slots 1-5 up to 8A/channel
n) L & LL modules can be used in slots 1-4 up to 25A/channel and in slot 5 up to 20A per channel
o) N & NN modules can be used in slots 1-5 up to 5A/channel for output voltages up to 29V. For output voltages 29.01 to 32V maximum rated current is 1A

p) P & PL modules 18-29V outputs can be used in slots 1-3 up to 5A and in slots 4-5 at up to 4A. 5-16V outputs can be used in slots 1-3 up to 8A and in slots 3-4 at up to 6A
q) Q & QQ modules can be used in slots 1-5 up to 25A/channel
r) R & RR modules can be used in slots 1-5 up to 60A/channel
s) S & SS modules can be used in slots 1/2 up to 75A, slots 2/3 up to 71A, slots 3/4 up to 69A & slots 4/5 up to 66A
t) T & TT modules can be used in slots 1-5 up to 60A
u) U & UU modules can be used in slots 1-3 up to 16A, slot 4 up to 15A and slot 5 up to 13A
v) W & WW modules can be used in slots 1-5 up to 15A/channel
w) Z & ZZ modules can be used in slots 1-4 up to 25A/channel and in slot 5 up to 20A per channel.
The following limitations also apply:
(a) For power supplies having one or more A, AA, AL, R, RR, T and/or TT modules and mounted vertically with the airflow downwards, the output is limited to 350W.
(b) For power supplies having one or more F or FF modules, the output is limited to 375W, only when operated in a vertical position with the fan on top of the power supply
(c) For power supplies fitted with an LSF option fan, the output is limited to 300W and 60AT. Operation in a vertical orientation with the fan at the top is not permitted
(d) For power supplies fitted with the fan reversed (RA option), the output is limited to 300W and 60AT. Operation in a vertical orientation is not permitted
(e) For power supplies having input or output connector housings fitted the total output is limited as follows:
PSU Orientation Total Power Output
Vertical with no fan P = 14.7 + 3.67*Vin
All other orientations P = 80 + 3.2*Vin
subject to a maximum total power output of 400W and a minimum mains input voltage of 90Vac. Where P = maximum total output power and Vin = mains input voltage
An example of product would be: CA400 @B @B @C @/@E or @_@E, @M where @ and @/@ or @_@ would be written on the product label as numbers representing the voltage of the module eg. 5B

Additional Module limitations:
When using remote sense, the max output voltage will be reduced by 0.5V for L, S, T, Q and R modules, and by 1.0V for C, D, F, G, J, M, K, N, U Modules.
Ampere turns for J module is calculated as AT =(output current + 15A) x 4
Adjusting output voltage beyond the stated range may cause overvoltage protection (OVP) to operate, whereby all outputs will turn off. To reset OVP, turn back output voltage adjustment and remove the mains supply for 30 seconds.

Additional Information

The schematics are kept on file at the CBTL and can be provided by the manufacturer upon request by NCB's/CBTL's.
The label sample represents all Models in the Series.
The original testing was carried out on the basis of 5 slots being filled, each slot being one 23mm module space wide. This is the maximum number of module slots allowed under this approval, and provides the worst case situation. Heating tests were carried out with the maximum number of slots filled, but with numerous loading conditions to cover any condition of loading in any slot position. Also, the models tested represent the least efficient, highest current module configurations. Abnormals were carried out on the expected worst case situation for that abnormal, and on as many configurations as considered necessary to represent the entire range of products covered by this approval. For the other tests, the conditions and configurations used were the expected worst case.
These products use optional coatings which are normally applied with a brush and are used within the primary area of the power supply on limited surface therefore deemed as non-safety critical. The coatings are not used for any safety purpose.
No Risk Management evaluation has been carried out on this product, therefore Essential Performance has not been specified, as this depends on the End Equipment.

Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

IEC 60601-1:2005, AMD1:2012, AMD2:2020

From Country Differences:

- United States of America: AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021
- Canada: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14

Additional Standards:

-

- The following additional investigations were conducted: -
- The product was not investigated to the following standards or clauses: -
- The following accessories were investigated for use with the product: None
- 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

  EMC compliance has not been verified nor has it been taken into consideration. An accredited EMC Test Report will be required in conjunction with the Certification of the end product.

  The product is Classified only to the following hazards: Casualty, Fire, Shock.

  Manufacturer's Recommended Ambient: 0 - 50°C

  Risk Management was excluded from this investigation.

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

Component was not preconditioned in humidity chamber before the tests. Humidity test shall be performed in end product.
The following Production-Line Tests are conducted for this product: Electric Strength, Earthing Continuity.
The End-Product Electric Strength Test it to be based upon a max working voltage of: Primary-Secondary: Vrms=336, Vpk=864 and Primary to Earthed Cover: Vrms=295, Vpk=400.
All outputs were individually referenced to earth to obtain max working voltage.
The Power Supply terminals and/or connectors are: Not investigated for field wiring.
The max investigated branch circuit rating is: 20A.
These products have been assessed for Class I, Pollution Degree 2, Material Group IIIB, Overvoltage category II, Altitude up to 3000 metres, Max Ambient 50 degrees C (higher ambient permitted for specific custom models).
Proper bonding to the End-Product main protective earthing termination is: Required.
The following magnetic devices (e.g. transformers or inductors) are provided with an OBJY3 insulation system with the indicated rating greater than Class A (105 degC). See critical components table for details.
The following End-Product enclosures are required: Fire, Mechanical and Electrical.
These units are internal forced-air cooled. They require a minimum of 50mm clearance in the vicinity of the ventilation holes. Whilst relatively orientation insensitive, operation of the these units when mounted vertically with the air flow in a downward direction is affected by convection acting against the cooling airflow, and results in slightly hotter temperatures (2 to 5 degrees) than if operated in the horizontal position. As a consequence of this, heating tests were carried out in the vertical orientation with airflow downwards to give the worst case temperatures, unless otherwise stated. No additional air flow during tests was applied, only the internal fans were used. ,
Consideration of spacings to the connections optional screw terminal input in the End-Product is required.
Output circuits have not been evaluated for direct patient connection (Type B, BF, CF)
This product must be installed in a restricted access location, accessible to authorised competent

personnel only.
Power Supply provides the following: 2 MOOPS isolation from Primary to Secondary; provides 1 MOOP isolation from Primary to Earth.
Considerations to the applied parts requirement, to be conducted as end-product.
Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end-use product shall ensure that the power supply is used within its ratings
The input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product
The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application
Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation
The PWB is rated: see table Critical Components
The products were tested on a 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary
The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
End product Risk Management Process to include consideration of requirements specific to the Power Supply.
Legibility of Marking to be considered / investigated in end use product. Durability test not conducted. ,
These products were considered to be a component part of a larger piece of Class 1 equipment. Full compliance with the standards will therefore depend on the installation in the final application. Some modules could present an energy hazard. Additionally, outputs can be connected in series thus producing non-SELV levels, or in parallel thus producing new energy hazards, and this must be taken into account in the end-use application. When non-seriesed outputs are earthed in the end use equipment they are SELV. If the outputs are not earthed they must be considered hazardous, as a single fault in the secondary may make them exceed the SELV limits between output and earth. If any output is non-SELV then all outputs become non-SELV
Leakage current measurements with non-frequency weighted measuring device shall be performed during end product evaluation.
The following secondary output circuits are at hazardous energy levels: modules A, AA, AL, C, CC, CH, D, DD, F, FF, G, GG, J, JJ, K, KK, R, RR, S, SS, T, TT, U and UU
The following secondary output circuits are at non-hazardous energy levels: modules B, BB, CL, CM, E, EB, EH, EL, EQ, H, L, LL, M, MM, N, NN, P, PL, Q, QQ, W, WW, Z and ZZ
Only L line is protected by a fuse. When power supply unit is used in not permanently connected installed equipment necessity of overcurrent protection in line N shall be considered.
End product Risk Management Process to include consideration of requirements specific to the Power Supply.
End product Risk Management Process to consider the need for simultaneous fault condition testing.
End product Risk Management Process to consider the need for different orientations of installation during testing.
End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
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.
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.
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

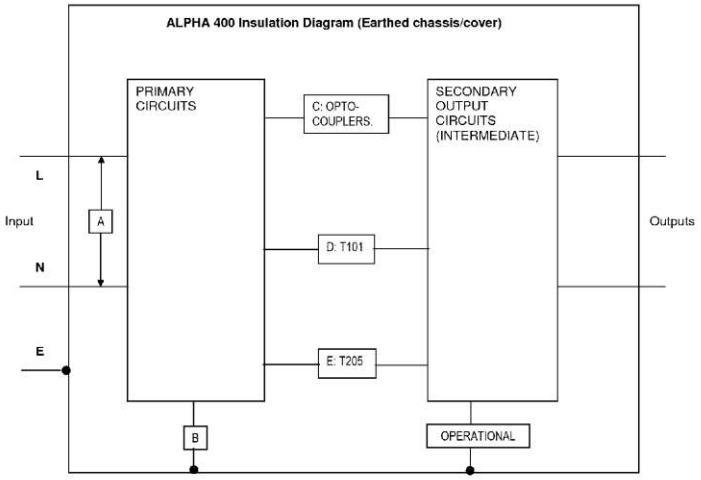
Report Modifications

Date Modified	Modifications Made (include Report Reference Number)	Modified By

(Year-Month-Day)		
2023-12-13	Unless otherwise indicated, all tests were conducted at TDK-Lambda Ltd., Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United Kingdom. Report was issued based on E349607-D7-CB-2 (issued: 2015-06-01) test report, test certificate no. DK-45831-M1-UL. No testing was considered necessary to meet the requirements of AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14, IEC 60601-1:2005, AMD1:2012, AMD2:2020 based on standard similarity. Following changes were introduced in comparison to E349607-D7-CB-2 (issued: 2015-06-01) test report: - addition of following components to list of critical components: alternatives for L4 earth choke, alternatives for C4, C5, C6, C7 Y capacitors, alternatives for C1, C2, C3 X capacitors, Core used in T205 (previously not exicitng on the list) - revisions of standards and certificates numbers on the list of critical components, - addition of national differences for Japan. No testing was considered necessary to introduce above mentioned changes.	Krzysztof Wasilewski
2024-03-13	This is a technical amendmend to the report E349607-D1028-1/A0/C0 to add an alternate L101 choke bobbin material. See Critical components table. After review of construction and documentation the device continues to comply with the requirements. No testing was considered necessary to introduce above mentioned changes.	Jakub Szymański

Insulation Diagram - (001) InsulationDiagramAndTable

INSULATION DIAGRAM



Insulation Diagram - (001) InsulationDiagramAndTable

TABLE: INSULATION DIAGRAM		
Pollution degree.....:	2	—
Overvoltage category.....:	II	—
Altitude.....:	3000m	—
Additional details on parts considered as applied parts.....:	None	—

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	Opposite Polarity	IIIb Assumed	240	340	3.0	1.9	3.7	3.7	Pass, Table 13, 16
B	1 MOOP	IIIb Assumed	295	400	3.2	2.3	4.5	2.7	Pass, Table 13, 16
C	2 MOOP	IIIb Assumed	240	340	4.8	4.6	8.2	8.2	Pass, Table 13, 16
D	2 MOOP	IIIb Assumed	316	496	6.7	5.1	8.2	8.2	Pass, Table 13, 16, 8, 14
E	2 MOOP	IIIb Assumed	336	864	7.0	6.3	8.8	8.8	Pass, Table 13, 16, 8

Supplementary information: Refer to CTL Decision DSH 0791 for circumstances when > (greater than) or < (less than) symbols are permitted. Measurements are from CB Scheme Test Report Ref. No. E349607-A2-CB-1 included in the test reference.

Linear interpolation between the nearest two values has been used for determining AIR clearances and Creepage distances, the required spaces have been rounded to next higher 0,1 mm.

For AIR clearances up to 3000 mt a Multiplication factor of 1,14 has been applied for MOOP

Supplementary Information: Tests were performed under CB Test Certificate Ref. No. DK-26881-UL dated 2012-07-03 prepared by UL International Demko A/S. These results have been included in this report for clarity.

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.