




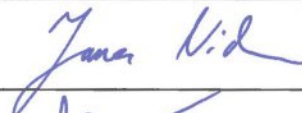
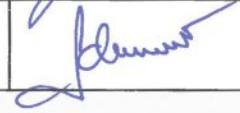
Test Report issued under the responsibility of:



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| TEST REPORT IEC 60601-1 Part 1: General requirements for basic safety and essential performance | |
| Report Number | T223-0128/16 |
| Date of issue | 2016-02-26 |
| Total number of pages..... | 529 pages |
| Name of Testing Laboratory preparing the Report..... | SIQ Ljubljana Testing Laboratory is accredited by Slovenian Accreditation, Reg. No.: LP-009 |
| Applicant's name..... | TDK-Lambda UK Ltd. |
| Address | Kingsley Avenue Ilfracombe, Devon EX34 8ES, United Kingdom |
| 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 |
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| 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 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. | |

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| Test item description.....: | Switching power supply for building-in |
| Trade Mark.....: |  |
| Manufacturer.....: | ARCH Electronics Corp. 7TH FL-1, No. 79, Sec. 1, Hsin Tai Wu Rd., Hsin Chin, New Taipei TW-221, Taiwan |
| Model/Type reference.....: | KMS15A-xx/yy-zzz, where: "xx" can be 3,75 ~ 5,25; 6,75 ~ 9,45; 9 ~ 12,6; 11,25 ~ 15,75 or 18 ~ 25,2 "yy" can be /blank or SC = Screw terminal chassis mount or SD = Screw terminal DIN rail mount "zzz" can be alphanumeric and does not have affect on safety KMS30A-xx/yy-zzz, where: "xx" can be 3,75 ~ 5,25; 9,0 ~ 12,6; 11,25 ~ 15,75 or 18,0 ~ 25,2 "yy" can be /blank or SC = Screw terminal chassis mount or SD = Screw terminal DIN rail mount "zzz" can be alphanumeric and does not have affect on safety KMS60A-xx/yy-zzz, where: "xx" can be 3,75 ~ 5,25; 6,75 ~ 9,45; 9 ~ 12,6; 11,25 ~ 15,75 or 18 ~ 25,2 "yy" can be /blank or SC = Screw terminal chassis mount or SD = Screw terminal DIN rail mount "zzz" can be alphanumeric and does not have affect on safety |

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| Ratings.....: | <p><u>Input:</u></p> <p>KMS15A-xx/yy-zzz; 100-240 Vac; 47-63 Hz; 0,385 Amax KMS30A-xx/yy-zzz; 100-240 Vac; 47-63 Hz; 0,65 Amax KMS60A-xx/yy-zzz; 100-240 Vac; 47-63 Hz; 1,5 Amax</p> <p><u>Output:</u></p> <p>KMS15A-xx/yy-zzz</p> <p>Where "xx" can be 3,75 ~ 5,25: 3,75 ~ 5,25 Vdc; 3 Amax.; Max. 15 W Where "xx" can be 6,75 ~ 9,45: 6,75 ~ 9,45 Vdc; 1,666 Amax.; Max.15 W Where "xx" can be 9,0 ~ 12,6: 9,0 ~ 12,6 Vdc; 1,25 Amax.; Max. 15 W Where "xx" can be 11,25 ~ 15,75: 11,25 ~ 15,75 Vdc; 1Amax.; Max.15 W Where "xx" can be 18,0 ~ 25,2: 18,0 ~ 25,2 Vdc; 0,625 Amax.; Max.15 W</p> <p>KMS30A-xx/yy-zzz</p> <p>Where "xx" can be 3,75 ~ 5,25: 3,75 ~ 5,25 Vdc; 5 Amax.; Max. 25 W Where "xx" can be 9,0 ~ 12,6: 9 ~ 12,6 Vdc; 2,5 Amax.; Max. 30 W Where "xx" can be 11,25 ~ 15,75: 11,25 ~ 15,75 Vdc; 2Amax.; Max.30 W Where "xx" can be 18,0 ~ 25,2: 18,0 ~ 25,2 Vdc; 1,25 Amax.; Max. 30 W</p> <p>KMS60A-xx/yy-zzz</p> <p>Where "xx" can be 3,75 ~ 5,25: 3,75 ~ 5,25 Vdc; 10 Amax.; Max. 51 W Where "xx" can be 6,75 ~ 9,45: 6,75 ~ 9,45 Vdc; 6,666 Amax.; Max.60 W Where "xx" can be 9,0 ~ 12,6: 9,0 ~ 12,6 Vdc; 5 Amax.; Max. 60 W Where "x" can be 11,25 ~ 15,75: 11,25 ~ 15,75 Vdc; 4 Amax.; Max. 60 W Where "x" can be 18,0 ~ 25,2: 18,0 ~ 25,2 Vdc; 2,5 Amax.; Max. 60 W</p> |
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| Testing procedure and testing location: | | |
| <input checked="" type="checkbox"/> | CB Testing Laboratory: | SIQ Ljubljana |
| Testing location/ address | | Tržaška cesta 2, SI-1000 Ljubljana, Slovenia |
| <input type="checkbox"/> | Associated CB Testing Laboratory: | |
| Testing location/ address | | |
| Tested by (name + signature)..... | | Janez Vidmar  |
| Approved by (name + signature)..... | | Gregor Schoss  |
| <input type="checkbox"/> | Testing procedure: TMP/CTF Stage 1: | |
| Testing location/ address | | |
| Tested by (name + signature)..... | | |
| Approved by (name + signature)..... | | |
| <input type="checkbox"/> | Testing procedure: WMT/CTF Stage 2: | |
| Testing location/ address | | |
| Tested by (name + signature)..... | | |
| Witnessed by (name + signature) | | |
| Approved by (name + signature)..... | | |
| <input type="checkbox"/> | 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):

1. Test Report (368 pages)
2. National Differences to IEC 60601-1: 2005 + AM1: 2012 – Enclosure No. 1 (60 pages)
3. Photo documentation – Enclosure No. 2 (19 pages)
4. Schematics, layouts and transformer drawings – Enclosure No. 3 (76 pages)
5. Triple insulated wire tested according to Annex L – Enclosure No. 4 (6 pages)

Summary of testing:

Tests performed (name of test and test clause):

- Clause 4.11: Power input
- Clause 7.1.3: Durability of marking test
- Clause 8.4.2: Working voltage/ power measurement
- Clause 8.4.3: ME equipment for connection to power source by a plug
- Clause 8.7: Leakage current
- Clause 8.8.3: Dielectric strength test of solid insulating materials with safety function
- Clause 8.8.4.1: Resistance to heat – ball pressure test of thermoplastics parts
- Clause 11.1.1: Excessive temperatures in ME equipment
- Clause 13.2: Single fault conditions in accordance with 13.2.2 to 13.2.13 inclusive
- Clause 15.3: Mechanical strength tests
- Clause 15.5.1.2: Transformer short circuit test
- Clause 15.5.1.3: Transformer overload test
- Annex L: Insulated winding wires for use without interleaved insulation
- Evaluation of voltage limiting components in SELV circuits

Testing location:

SIQ Ljubljana
Tržaška cesta 2, SI-1000 Ljubljana, Slovenia

Summary of compliance with National Differences

List of countries addressed: See Enclosure No. 1 for details.

The product fulfils the requirements of IEC 60601-1:2005 + A1:2012 and EN 60601-1:2006 + A1:2013 + A12:2014

Copy of marking plate:

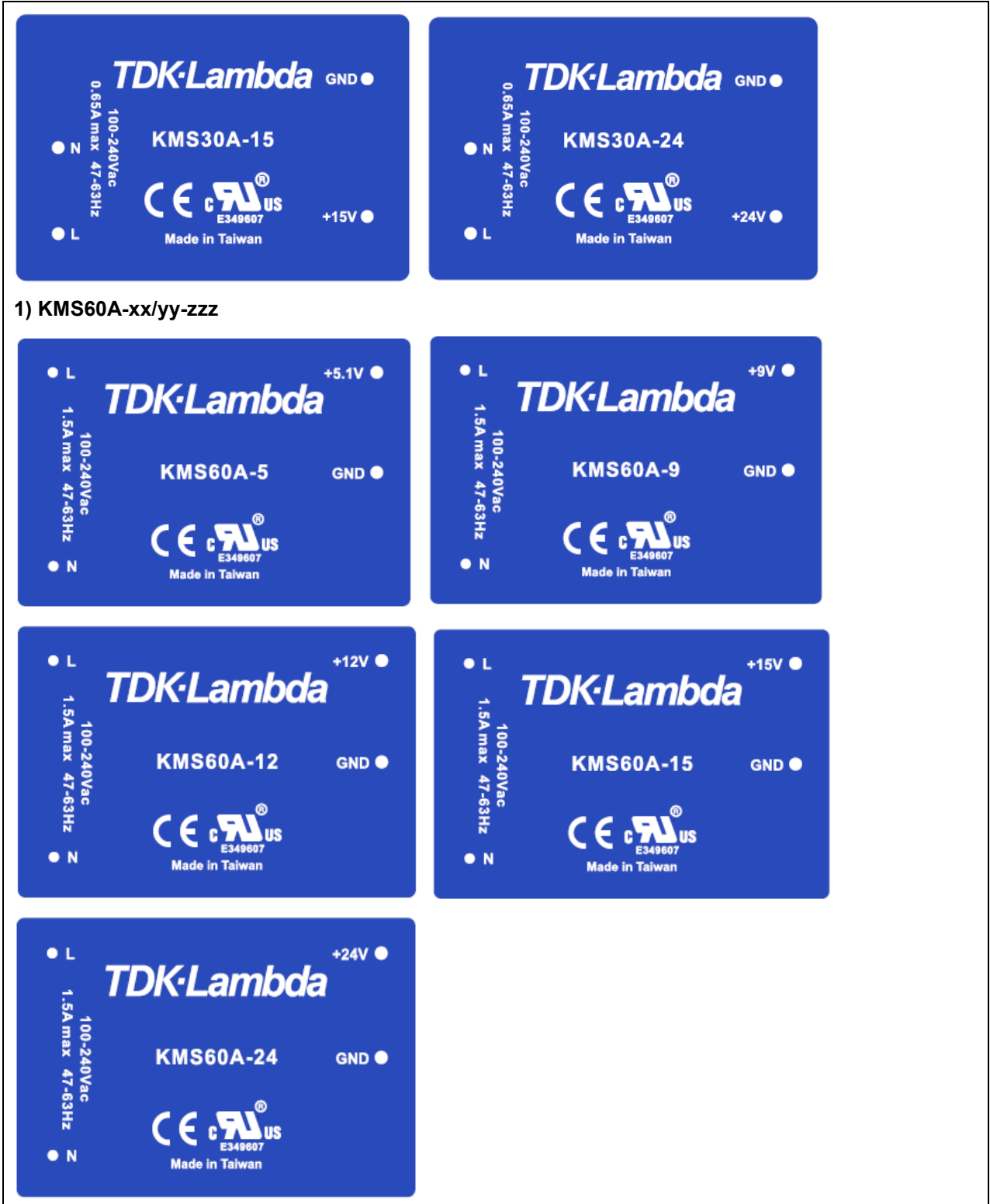
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

1) KMS15A-xx/yy-zzz



1) KMS30A-xx/yy-zzz





| GENERAL INFORMATION | | | |
|------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------|
| Test item particulars (see also Clause 6): | | | |
| Classification of installation and use..... : | Power supply unit is intended for building-in. | | |
| Device type (component/sub-assembly/ equipment/ system): | Component. | | |
| Intended use (Including type of patient, application location) : | Power supply unit is intended for building-in to provide power to medical devices with isolation grade MOPP (MOPP achieved between input and output). | | |
| Mode of operation..... : | Continuous operation. | | |
| Supply connection | Power supply unit is intended for building-in and provided with: - Input/output pins for soldering within end medical product (KMS15A-xx, KMS30A-xx, KMS60A-xx) - Screw terminals for input/output wires connection (KMS15A-xx/SC, KMS15A-xx/SD, KMS30A-xx/SC, KMS30A-xx/SD, KMS60A-xx/SC, KMS60A-xx/SD) | | |
| Accessories and detachable parts included | No accessories and detachable part included. | | |
| Other options include..... : | No other options included. | | |
| Testing | | | |
| Date of receipt of test item(s) | 2015-03-24, 2015-04-01, 2015-04-17 2016-02-19 (Rev. 1.0) | | |
| Dates tests performed | From 2015-03-30 to 2015-07-01 From 2016-02-23 to 2016-02-23 (Rev. 1.0) | | |
| 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 |

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| <p>General remarks:</p> <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.</p> <p>Throughout this report a <input checked="" type="checkbox"/> comma / <input type="checkbox"/> point is used as the decimal separator.</p> <p>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.</p> | |
| <p>Manufacturer's Declaration per sub-clause 4.2.5 of IEC 60601-1:2005</p> | |
| <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 style="text-align: right;"> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not applicable </p> | |
| <p>When differences exist; they shall be identified in the General product information section.</p> | |
| <p>Name and address of factory (ies)..... : ARCH Electronics Corp. 7TH FL-1, No. 79, Sec. 1, Hsin Tai Wu Rd., Hsin Chin, New Taipei TW-221, Taiwan</p> | |
| <p>General product information:</p> <p>EUT is power supply unit intended for building-in provided with a single power output and with universal input range 100-240 Vac.</p> <p>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.</p> <p>Power supply unit is provided with input and output pins intended for soldering to the PCB within end product (KMS15A-xx, KMS30A-xx, KMS60A-xx) or with screw terminals for input/output wires connection (KMS15A-xx/SC, KMS15A-xx/SD, KMS30A-xx/SC, KMS30A-xx/SD, KMS60A-xx/SC, KMS60A-xx/SD).</p> <p>In model designation KMS15A-xx/yy-zzz: "xx" can be 3,75 ~ 5,25; 6,75 ~ 9,45; 9 ~ 12,6; 11,25 ~ 15,75 or 18~25,2 and denotes DC output voltage "yy" can be /blank or SC = Screw terminal chassis mount or SD = Screw terminal DIN rail mount "zzz" can be alphanumeric and does not have affect on safety</p> <p>In model designation KMS30A-xx/yy-zzz: "xx" can be 3,75 ~ 5,25; 9,0 ~ 12,6; 11,25 ~ 15,75 or 18,0 ~ 25,2 and denotes DC output voltage "yy" can be /blank or SC = Screw terminal chassis mount or SD = Screw terminal DIN rail mount "zzz" can be alphanumeric and does not have affect on safety</p> <p>In model designation KMS60A-xx/yy-zzz: "xx" can be 3,75 ~ 5,25; 6,75 ~ 9,45; 9~12,6; 11,25 ~ 15,75 or 18 ~ 25,2 and denotes DC output voltage "yy" can be /blank or SC = Screw terminal chassis mount or SD = Screw terminal DIN rail mount "zzz" can be alphanumeric and does not have affect on safety</p> | |

For output rating of each model, see table on page 2 for details.

KMS15A-xx/yy-zzz: PCB with dimension 50,1 mm by 25,0 mm is used.

Additional PCB for KMS15A-xx/yy-zzz (yy can be SC or SD): 92,5 mm by 50,5 mm is used.

KMS30A-xx/yy-zzz: PCB with dimension 60 mm by 41,5 mm is used.

Additional PCB for KMS30A-xx/yy-zzz (yy can be SC or SD): 92,5 mm by 50,5 mm is used.

KMS60A-xx/yy-zzz: PCB with dimension 85 mm by 60 mm is used.

All the transformers have similar construction, transformer construction details of model KMS15A-xx/yy-zzz, KMS30A-xx/yy-zzz and KMS60A-xx/yy-zzz are specified in Enclosure No. 3

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

Explanation of the test program:

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.

The unit is medical power supply unit intended for building-in and provided with plastic enclosure (filled with insulation compound to improve rigidity of the enclosure). Enclosure is considered as part that cannot be touched by the operator when installed within the end medical product.

The unit provides internally one primary fuse. Primary fuse not accessible due the power supply unit is additionally filed with insulation compound. Additionally for models KMS15A-xx/SC-zzz, KMS15A-xx/SD-zzz, KMS30A-xx/SC-zzz, KMS30A-xx/SD-zzz, KMS60A-xx/SC-zzz, KMS60A-xx/SD-zzz external fuse is provided.

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

- 2 x MOPP between primary and secondary circuit

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 electrical specifications.

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

The transformers T1 provide reinforced insulation. These transformers are built up to fulfil the requirement of insulation class B.

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

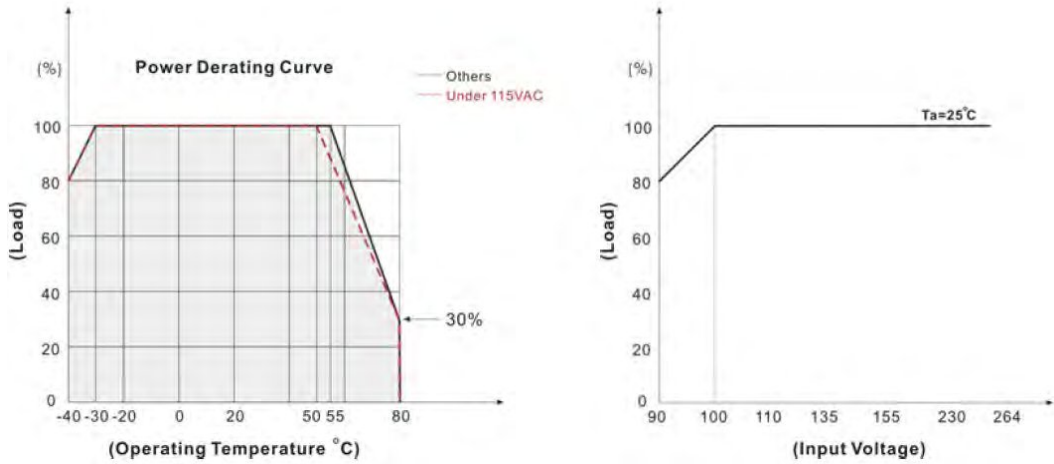
Multiplication factor 1,48 used for required clearance distance for parts of opposite polarity.

Multiplication factor 1,29 used for required clearance distance between primary and secondary.

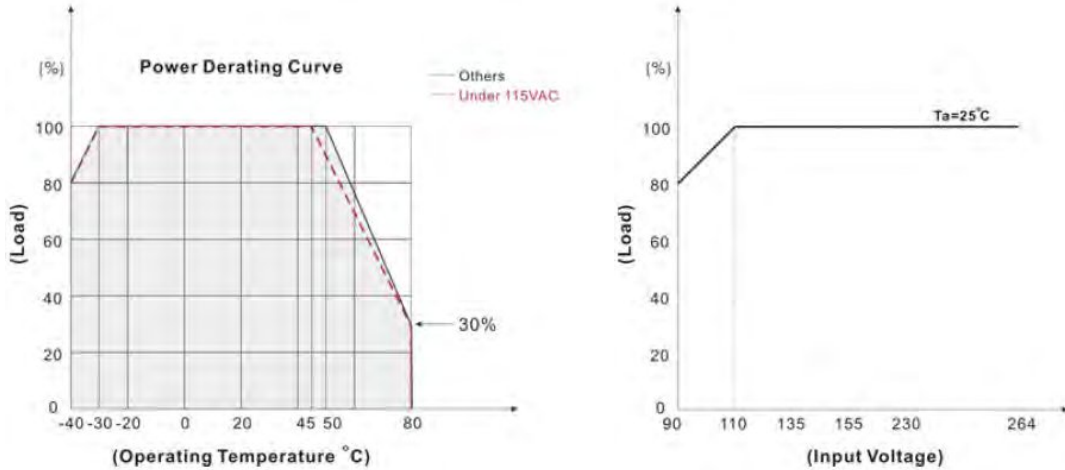
Power supply unit is provided with plastic enclosure made by non-flammable material V-0.

The power supply is maintenance free.

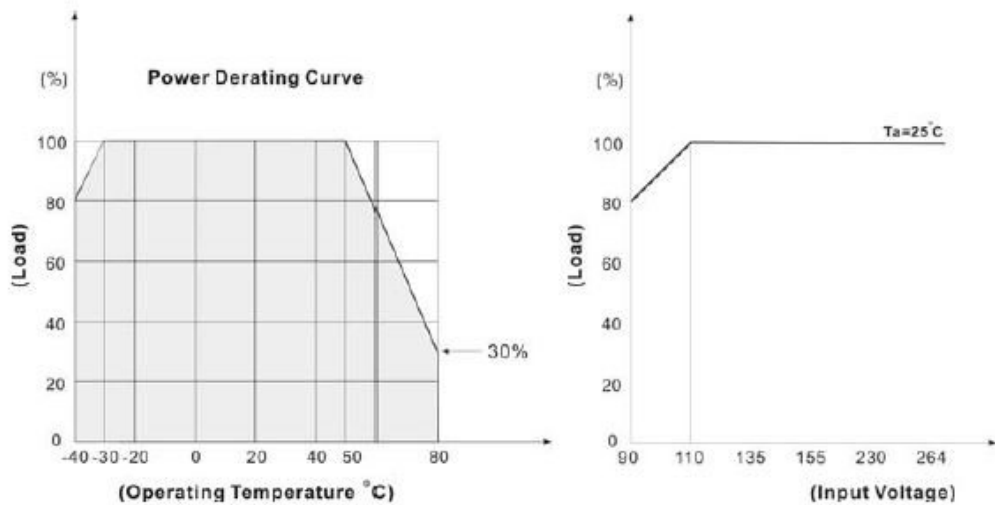
The power supplies KMS15A-xx/yy-zzz are intended for operating at ambient temperature up to 50°C (without derating) or up to 80°C (with derating). Additional derating at input voltage below 115Vac. See charts below.



The power supplies KMS30A-xx/yy-zzz are intended for operating at ambient temperature up to 50°C (without derating) or up to 80°C (with derating). Additional derating at input voltage below 115Vac. See chart below.



The power supplies KMS60A-xx/yy-zzz are intended for operating at ambient temperature up to 50°C (without derating) or up to 80°C (with derating):



The unit shall not be used for use in an oxygen rich environment.
 The unit it is not intended to be use with flammable anesthetics and not intended for use in conjunction with flammable agents.

| History Sheet | | | |
|---------------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| Date | Report Number | Change | Revision No. |
| 2015-10-06 | T223-0313/15 | Initial Test Report issued. | — |
| 2016-02-26 | T223-0128/16 | Test report reviewed and updated due to new printing method of the label on plastic enclosure. After review the following test was considered necessary: - Table 7.1.3: Durability of marking test. No other changes. | 1.0 |

Technical Considerations:

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

- Clause 7.5 (Safety Signs),
- Clause 7.9 (Accompanying Documents),
- Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- Clause 10 (Radiation),
- Clause 14 (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 25,5°C, 92,0%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.