Description

UL TEST REPORT AND PROCEDURE

Standard:	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
Certification Type:	Component Recognition
CCN:	QQHM2 / QQHM8
Complementary CCNs:	
Product:	Medical Switch Mode Power Supply
Model:	EFE400Mxy-a-b-cdef-gh-i-j-klm or EFE-400M-a-b-cdef-gh-i-j-klm Units may be marked with a Product Code: U6x or Y6x where x may be any number of characters. Unit Configuration Code (Description :) may be prefixed by NS # followed by / or - (where # may be any number of characters indicating non- safety related model differences). Unit Configuration Code (Description :) may be prefixed by SP followed by / or (SP represents a sales code) Where: x = blank or J y = blank, P or D a = Channel one output voltage and can be from 11.4 to 50 b = Standby voltage 5 or 12 c = BC, HN, HU, HC, EC, NN, NU, NC, HP, NP or TF d = M or S e = D, F, E or G f = L, R, T or Z g = Y or N h = T, E or N i = V or blank j = blank, xD, xPD klm = number from 0-9 or Blank Non-standard models Y60001#
Rating:	100-240Vac nom, 45-63Hz, 6.1A rms max. (See Model Differences for details of ratings)
Applicant Name and Address:	TDK-LAMBDA UK LTD KINGSLEY AVE, ILFRACOMBE DEVON EX34 8ES, UNITED KINGDOM

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability as applicable.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by:	Kamil Janeczek, Project Handler	Reviewed by:	Grzegorz Kowalski, Reviewer

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

i. **Part AC** details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.

ii. **Part AE** details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.

iii. **Part AF** details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Product Description

Medical Switch Mode Power Supply (see Model Differences for details of models and nomenclature)

- The product was not investigated to the following standards or clauses:: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is:: Ordinary
- The mode of operation is:: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:: No
- Risk Management has not been applied to these products.
- Options include a variable speed (temperature controlled) fan.
- Multilayer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report Enclosure 8-05 of this report.

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.

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

Model Differences

EFE400Mxy-a-b-cdef-gh-i-j-klm or EFE-400M-a-b-cdef-gh-i-j-klm models as described below:

Units may be marked with a Product Code: U6x or Y6x where x may be any number of characters.

Unit Configuration Code (Description :) may be prefixed by NS # followed by / or - (where # may be any number of characters indicating non- safety related model differences).

Unit Configuration Code (Description :) may be prefixed by SP followed by / or – (SP represents a sales code)

Unit Configuration Code: EFE400Mxy-a-b-cdef-gh-i-j-klm where:
x = Nothing or J for Japanese models (may have non-safety differences).

y = Blank for Y2 capacitors from output to earth P for Y1 capacitors from output to earth
D for Class II (with Y1 capacitors)

a = Channel 1 output Voltage (see Ch1 in the table below, adjustment range column).
b = Standby voltage: see standby voltage in table below.
c = BC for cover and U chassis without fan grill, with fan fitted (temperature controlled). (Y60001x model only)
HN for Open frame, no fan, with 12V / 1A fan supply.
HU for U chassis (not EFE400MxD models), no fan, with 12V / 1A fan supply.
HC for Cover + chassis (not EFE400MxD models), no fan, with 12V / 1A fan supply.
EC for Cover + chassis (not EFE400MxD models), end fan (temp controlled).
NN for Open frame, no fan, no fan supply.
NU for U chassis (not EFE400MxD models), no fan, no fan supply.
NC for Cover + chassis (not EFE400MxD models), no fan, no fan supply.
HP for perforated cover, no fan, with 12V / 1A fan supply.
NP for perforated cover, no fan, no fan supply.
TF for Cover + chassis (not EFE400MxD models), top fan (fixed speed)

d = M for Molex KK type 41791 input connector or equivalent.
S for Molex Sabre type 43160 input connector or equivalent.

e = D for AC input with dual fusing.
F for AC/DC input with dual fusing.
E for single fuse input in the Live line.
G for single fuse input in the + line

f = L for low Leakage.
R for reduced Leakage.
T for tiny Leakage.
Z for EFE400MxD models (Class II).
where L < 300uA leakage, R < 150uA leakage and T < 75uA leakage.

g = Y for Oring FET included.
N for no Oring FET.

h = T for inhibit.
E for enable.
N for no remote signals

i = V for vertical output connector or nothing for horizontal output connector.

j = Nothing for standard channel 1 output voltage, xD or xPD where D is for units with programmed negative load regulation, PD is for units with programmed positive load regulation, x is the voltage of the regulation in 100mVolts and is within the Output Adjustment range (example, 7D = 0.7V of negative load regulation, 18PD = 1.8V of positive load regulation).

klm = Three numbers from 0 to 9 which denotes various output voltage/current settings within the specified ranges of each output for a particular unit or blank for standard output settings. (may define non-safety related parameters/feature, e.g. reduced primary current limit, reduced OVP)

Input Parameters

Standard	60601-1
Nominal input voltage	100 - 240 Vac
Input voltage range	90 - 264Vac*
Input frequency range	45 - 63Hz

Maximum input current 6.1A rms
* Input de-rated, see variations and limitations below.
All ratings apply for ambient temperatures up to 50°C. (see variations and limitations below)
Output Parameters
There are three EFE400M standard models and two non-standard models with various options and output parameters shown in the tables below.

Standard models:

	Vout Nom.	Adjustment Range (V)	Output Current (A)	Maximum Power (W)
Output Channel 1	12	11.4 - 13.2*	33.33	400 (530**)
	24	22.8 - 26.4*	16.67	400 (530**)
	48	47 - 50*	8.33	400 (470**)
Fan output (optional)	12	12	1	12
	5	5	2	10
	12	12 - 12.2*	1	12.2

Variations and limitations of use for Standard models:

1. Output power de-rated 1% per volt from 100V to 90V input (channel 1 power 360W at 90V input).
2. Output power further de-rated 2% per volt from 90V to 85V input (channel 1 power 320W at 85V input).
3. Maximum ambient 70°C (de-rating output power 2.5% per °C above 50°C).
4. * Can be adjusted at the factory only.
5. Maximum continuous power output 400W (including fan output).
6. ** Peak power for 10 seconds maximum, maximum rms power of 400Wrms: Non-Standard Models:

Non- Standard model: Y60001# (# can be any letter) (EFE400M-48-5-BCSDL-NT)

Output Channel	Vout Nom.	Adjustment Range (V)	Output Current (A)	Maximum Power (W)
Channel 1	48	47 to 50*	8.33	400
Standby output	5	fixed	2	10

Variations and limitations of use for Non- Standard model Y60001#:

1. Output power de-rated 1% per volt from 100V to 90V input. (e.g. channel 1 power 360W at 90V input)
2. Maximum ambient 50°C.
3. * Can be adjusted at the factory only.

The limited testing of this report (see Report Modifications section) was conducted by TDKLAMBDA UK LTD in KINGSLEY AVE, ILFRACOMBE, EX34 8ES United Kingdom, under CTF Stage 3 Test Procedures for CB certification.

The following tests were selected as representative of the test program applicable to model covered by this CBTR:
8.8.3 Dielectric Voltage Withstand
11.1.1 Temperature Measurement
13 Abnormal Operation Testing (output short circuit)

These tests have been witnessed for models selected as representative of the standard covered by this report and the applicable test program.

Additional Information
Cooling for units with customer supplied air (all models except -BC and -EC) The following method must be used for determining the safe operation of PSUs.
The components listed in the following table must not exceed the temperatures given. To determine the component temperatures the heating tests must be conducted in accordance with the requirements of the standard in question. Consideration should also be give to the requirements of other safety standards. Test requirements include: PSU to be fitted in its end-use equipment and operated under the most adverse

conditions permitted in the end-use equipment handbook/specification and which will result in the highest temperatures in the PSU. To determine the most adverse conditions consideration should be given to the end use equipment maximum operating ambient, the PSU loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers, etc. Temperatures should be monitored using type K fine wire thermocouples (secured with cyanoacrylate adhesive, or similar) placed on the hottest part of the component (out of any direct airflow) and the equipment should be run until all temperatures have stabilized. Cooling for unit temperature table (see layout drawings below):

Circuit Ref.	Description	Max. Temperature (°C) †
J1	input connector	105 (75††)
C12, C8, C7	X cap	100
L1, L2	Common mode choke winding	130 (145)
L6	Series mode choke winding	130
TX1	Standby trx winding	130
U2, U3, U5, U6, U7	Opto-coupler	100
TX2	Primary, secondary windings and core	130
C5	Capacitor	85 (105)
C9	Boost capacitor	70 (105)
L3	Boost choke winding	130 (140)
L7	Channel 1 output choke	130
XQ225	Boost FET (ASY2 primary IMS)	125 (130)
Q2	Channel 1 output FET (ASY4 secondary IMS)	125 (130)
L8	Primary resonant choke (not 12V model)	130 (140)
J2	Output connector	105
XL701	fan output choke	110 (125)
C1, C11, C19, C20	Electrolytic capacitors	75 (105)

† The higher temperatures limits in brackets may be used but product life may be reduced. Cooling for units with customer supplied air (all models except -BC and -EC)

Technical Considerations

- The product was investigated to the following additional standards: EN 60601-1:2006/A2:2021 (IEC60601-1, Edition 3.2)

- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Clause 4.2 RISK MANAGEMENT PROCESS, Clause 12.2 USABILITY, Clause 14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS, Clause 17 Electromagnetic Compatibility (IEC 60601-1-2) and Clause 11.7 Biocompatibility (ISO 10993-1)
- The following accessories were investigated for use with the product: None
- None

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. When installed in an end-product, consideration must be given to the following:

- • When installed in an end-product, consideration must be given to the following:
  - The following Production-Line tests are conducted for this product: Electric Strength, Earthing Continuity
  - The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary- SELV: 396 Vrms, 922 Vpk, Primary-Earthed Dead Metal: 381 Vrms, 672 Vpk, Secondary outputs - Earthed Dead Metal: 240Vrms, 340Vpk.
  - The following secondary output circuits are SELV: All
  - The following secondary output circuits are at hazardous energy levels: Channel 1
  - The following secondary output circuits are at non-hazardous energy levels: Standby supply, fan output
  - The following output terminals were referenced to earth during performance testing: All outputs and their return lines individually referenced to earth to obtain maximum working voltage.

- The power supply terminals and/or connectors are: Not investigated for field wiring
- The maximum investigated branch circuit rating is: 20 A
- Proper bonding to the end-product main protective earthing termination is: Required
- An investigation of the protective bonding terminals has: Been conducted
- The following magnetic devices (e.g. transformers or inductor) are provided with a Class F (155°C) insulation system: Transformer TX1 and TX2 - See table 8.10 for details of insulation systems used
- The following end-product enclosures are required: Fire, Mechanical, Electrical

The following components require special consideration during end-product Thermal (Heating) tests due to the indicated maximum temperature measurements during component-level testing:
Models without a fan require component temperatures monitored as detailed in the Additional Information.

- For open frame models H4 is the PWB fixing point connecting to J1 protective earth.
- The equipment has been evaluated as a Class 1 unit (and Class II for EFE400MxD models), but is not intended to be used to terminate the end equipment to the incoming mains supply. Need for PE marking shall be determined in the end product investigation.
- No essential performance has been considered
- The risk management requirements of the standard were not addressed and must be considered in the end product investigation.
- Output circuits have not been evaluated for direct patient connection (Type B, BF or CF)
- The product was submitted and evaluated for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification of: 70°C (output de-rated 2.5% per °C above 50°C).
- Insulation separation between: Secondary and Earth is one MOPP: 240Vrms, 340Vpeak
- Insulation separation between: Primary and Earth is one MOPP: 381Vrms, 672Vpeak
- Insulation separation between: Primary and secondary is 2 MOPP: 396Vrms, 922Vpeak
- Altitude of operation: 3000m
- The perforated cover when fitted to the EFE400MxD models (Class II) must be treated as a live part with 1 MOPP insulation to primary and 1 MOPP insulation to secondary.

Clause 8.7 Leakage Currents and Patient Auxiliary Currents for EFE400MxD models requires assessment in the end equipment.