Page 1 of 147 Report No.: E321744-D1018-1/A0/C0-ULCB



Test Report issued under the responsibility of:



# IEC 60601-1 Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

Report Reference No. ...... E321744-D1018-1/A0/C0-ULCB

Date of issue ...... 2018-09-28 (A0/C0)

Total number of pages .....: 147

CB Testing Laboratory ...... UL Brea

Applicant's name ...... XP POWER L L C

Address ...... 15641 RED HILL AVE, SUITE 100

TUSTIN CA 92780 USA

Test specification:

Standard ...... IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007

+ A1:2012

(or IEC 60601-1: 2012 reprint)

Test procedure ...... CB Scheme

Non-standard test method...... N/A

Test Report Form No...... IEC60601 1K

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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:	Compo	onent DC-to-DC Converter	
Trade Mark:	X	P	
Manufacturer:	Same	as Applicant	
Model/Type reference:	represo output	ixxSyyy and IMM05xxDyyy (w enting input voltage; yyy is 3V voltage)	'3, 05, 12 or 15 representing
Ratings:		c to 9 Vdc, 9Vdc to 18Vdc, or t markings of 5 Vdc, 12 Vdc, o	18Vdc to 36Vdc corresponding or 24 Vdc respectively
Testing procedure and testing location	, <u>.</u>		
[X] CB Testing Laboratory:	-		
Testing location/ address:		UL Brea	
[] Associated CB Testing Laborato	nrv.	2929 E Imperial Hwy Ste 10	0, Brea CA 92821, USA
Testing location/ address:	·· y ·		
Tested by (name, function, signatu	re).	Rahul Baria, Project	
rested by (name, function, signatu	10).	Handler	Rahul Baria
Approved by (name, function, signa	ature):	Ahmad Daoudi, Project Reviewer	ALSO S.
[] Testing procedure: CTF Stage 1	:		
Testing location/ address:			
Tested by (name, function, signatu	re):		
Approved by (name, function, signa	ature):		
[] Testing procedure: CTF Stage 2	2		
Testing location/ address:			
Tested by (name, function, signatu	re):		
Witnessed by (name, function, sigr	nature):		
Approved by (name, function, signa	ature):		
[X] Testing procedure: CTF Stage 3	):		
[] Testing procedure: CTF Stage 4	:		
Testing location/ address:		XP Power Limited, 401 Com Technocentre, Lobby B, #02	
Tested by (name, function, signatu	ŕ	Alicia Chiang - Tester	Alin
Witnessed by (name, function, sign	nature):		

Page 3 of 147 Report No.: E321744-D1018-1/A0/C0-ULCB

Supervised by (name, function, signature):	Rahul Baria - Project Handler	Rahul	Baria
, , ,	Ahmad Daoudi - Project Reviewer	Alelo	$\int$ $\int$ .

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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 D of this report if testing was performed as part of this evaluation.

Summary of compliance with National Differences

List of countries addressed: Austria, Korea, Republic of, USA, Canada, United Kingdom, Sweden

[X] The product fulfils the requirements of <u>IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012</u>

(or IEC 60601-1: 2012 reprint).

Page 5 of 147 Report No.: E321744-D1018-1/A0/C0-ULCB

# 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.

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**GENERAL INFORMATION** 

Test item particulars (see also Clause 6):

Classification of Installation and Use:

Device type (component/sub-assembly/ equipment/ system):

Component

Intended use (Including type of patient, application location): Component DC-DC converter for use in

medical power supplies

Mode of Operation: Continuous

Supply Connection:

Accessories and detachable parts included:

Other Options Include:

None

None

Testing

Possible test case verdicts:

- test case does not apply to the test object ...... N/A

- test object was not evaluated for the requirement .....: N/E

- 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 point is used as the decimal separator.

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 .....

Not Applicable

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

Name and address of factory (ies) ...... Motien Technology Co Ltd

9 Keji 2nd Rd Technology Industrial Park

Tainan 70955 TAIWAN

### **GENERAL PRODUCT INFORMATION:**

### **Report Summary**

All applicable tests according to the referenced standard(s) have been carried out.

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

### **Product Description**

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The unit is a component dc to dc Converter to be used as part of Medical Electrical Equipment, and is intended to provide one MOPP between input circuits to output circuit

### **Model Differences**

IMM05xxSyyy and IMM05xxDyyy, where xx is 05, 12, or 24 representing input voltage; and yyy is 3V3, 05, 12, or 15 representing output voltage

Model IMM05xxDyyy Series is identical to Model IMM05xxSyyy Series except it is provided with two outputs instead of one.

All models within a series are identical except for transformer windings, inductance and MOSFETs, and output ratings.

See below for Model Output Ratings @ 60°C.

IMM05XXS3V3: 3.3Vdc, 1200mA IMM05XXS05: 5 Vdc, 1000mA IMM05XXS12: 12Vdc, 416mA IMM05XXS15: 15Vdc, 333mA

IMM05XXD12: +12Vdc, 208mA; -12Vdc, 208mA IMM05XXD15: +15Vdc, 166mA; -15Vdc, 166mA

Where XX can be 05, 12, or 24, and denotes nominal input voltage ranges as follows:

05 = 4.5-9Vdc 12 = 9-18Vdc 24 = 18-36Vdc

### **Additional Information**

Marking label submitted is representative of all models in this Report (input ratings may vary).

When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

### **Technical Considerations**

The product was investigated to the following standards:

### Main Standard(s):

ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)

# From Country Differences:

- Austria: EN 60601-1:2006/A1:2013
- Korea, Republic of: KS C IEC 60601-1
- USA: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
- United Kingdom: BS EN 60601:2006 A1
- Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

Additional Standards: EN 60601-1:2006 / A1:2013 / A12:2014

- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Biocompatibility, EMC,

Annex Z of EN standards for compliance with the MDD

- 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
- Scope of this evaluation defers the following clauses to the be determined as part of the end product: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME
- Hazard), Clause 10 (Radiation), Clause 16 (ME Systems).
- Scope of this evaluation excludes the following: Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15; Battery related clauses: 7.3.3, 15.4.3; Hand
- Control related clauses: 8.10.4; Oxygen related clauses: 11.2.2; Fluids related clauses: 11.6.2 11.6.4; Sterilization clause: 11.6.7; Biocompatibility Clause: 11.7 (ISO 10993); Motor
- related clauses: 13.2.13.3, 13.4; Heating Elements related clause: 13.2; Flammable Anaesthetic Mixtures Protection: Annex G.

### **Engineering Conditions of Acceptability**

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

This component dc to dc converter has been judged on the basis of the required creepage and clearances for 1 MOPP based on a working voltage of 250Vrms, 354Vpk between input and output circuits at an altitude of 5000m in accordance with Standard for Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance, ANSI/AAMI ES 60601-1:2005 (R) 2012, CSA C22.2 No. 60601-1:2014 and IEC 60601-1, Edition 3.1, Sub-clause 8.9, which covers the end-use product for which the component was designed

The unit is a DC/DC converter and not evaluated for the separation to SUPPLY MAINS; suitable MAINS separation shall be provided during final installation

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 product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 60°C at Full Load

The output circuit has not been evaluated for connecting to Applied Parts. For end products intended to connect to Applied Parts, suitable evaluation should be considered

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 dc-to-dc converter is used within its ratings

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

TRF No. IEC60601\_1K

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### Supply.

End product Risk Management Process to consider the need for simultaneous fault condition 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 Leakage of Liquids 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

The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.

The label has not been evaluated, the need to conduct the durability of marking and legibility of marking tests should be determined in the end product.

The product is a component for building in, the accessibility shall be determined as part of the end product investigation.

### **Report Modifications**

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By

Page 1 of 148 Report No.: E321744-D1018-1/A1/C0-CB



Test Report issued under the responsibility of:



# IEC 60601-1 Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

Report Reference No. ...... E321744-D1018-1/A1/C0-CB

Date of issue ...... 2018-11-2

Total number of pages .....: 148

CB Testing Laboratory .....: UL Brea

Applicant's name.....: XP POWER L L C

Address .....: 15641 RED HILL AVE, SUITE 100

TUSTIN CA 92780 USA

Test specification:

Standard...... : IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007

+ A1:2012

(or IEC 60601-1: 2012 reprint)

Test procedure .....: CB Scheme

Non-standard test method.....: N/A

Test Report Form No. ..... IEC60601\_1K

Test Report Form Originator .....: UL(US)

Master TRF ...... 2015-11

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Test item description: Trade Mark:  Manufacturer:  Same as Applicant  Model/Type reference: IMM05xxSyyy and IMM05xxDyyy (where xx is 05, 12, or 24 representing input voltage; yyy is 3V3, 05, 12 or 15 representing output voltage; input voltage; yyy is 3V3, 05, 12 or 15 representing output voltage; input vo			
Manufacturer:   Same as Applicant	Test item description:	Compo	nent DC-to-DC Converter
Model/Type reference:	Trade Mark:		
Ratings:   Input voltage; yyy is 3V3, 05, 12 or 15 representing output voltage)   Input voltage (Vdc):   IMM0505Dyyy 4.5-9   IMM0505Dyyy 4.5-9   IMM0512Dyyy 9.18   IMM0512Dyyy 9.18   IMM0512Dyyy 18-36   IMM0524Dyy; 18-36   IMM0524Dyy; 18-36   IMM0505S3V3 1100   IMM0505S3V3 1100   IMM0505S12 1372   IMM0505S12 1372   IMM0505S12 1372   IMM0505D15 1389   IMM0505D15 1389   IMM0512S15 678   IMM0512S12 678   IMM0512S12 678   IMM0512S15 678   IMM0512D12 686   IMM0512D15 686   IMM0512D15 686   IMM0512D15 686   IMM0512D15 686   IMM0524S3V3 275   IMM0524S3V3 275   IMM0524S3V3 275   IMM0524S3V3 275   IMM0524S3V3 275   IMM0524S3V3 275   IMM0512D15 339   IMM0524D12 339   IMM0524D12 339   IMM0524D12 339   IMM0524D12 339   IMM0524D12 339   IMM0524D15 339   Output: Refer to model differences.  Testing procedure and testing location:   IX	Manufacturer:	Same a	as Applicant
Input voltage (Vdc):   IMM0505Sypy 4.5-9   IMM0505Sypy 4.5-9   IMM0505Sypy 9.18   IMM0512Sypy 9.18   IMM0512Sypy 9.18   IMM0512Sypy 9.18   IMM0524Sypy 18-36   IMM0524Dypy 18-36   IMM0505S3V3 1100   IMM0505S3V3 1100   IMM0505S05 1372   IMM0505S12 1372   IMM0505S12 1372   IMM0505D12 1389   IMM0505D12 1389   IMM0512S12 678   IMM0512S12 678   IMM0512S12 678   IMM0512S12 678   IMM0512D12 686   IMM0512D12 686   IMM0524S3V3 275   IMM0524S3V3 275   IMM0524S3V3 275   IMM0524S12 335   IMM0524D12 339   IMM0524D12 339   IMM0524D12 339   IMM0524D12 339   IMM0524D12 339   IMM0524D15 339	Model/Type reference:	represe	enting input voltage; yyy is 3V3, 05, 12 or 15 representing
IMM0505S3V3 1100   IMM0505S05 1372   IMM0505S12 1372   IMM0505S15 1355   IMM0505D12 1389   IMM0505D15 1389   IMM0512S3V3 550   IMM0512S12 678   IMM0512S12 678   IMM0512D12 686   IMM0512D12 686   IMM0512D15 686   IMM0512D15 686   IMM0524S3V3 275   IMM0524S3V3 355   IMM0524S12 335   IMM0524S12 335   IMM0524S12 335   IMM0524S12 339   IMM0524D12 339   IMM0524D12 339   IMM0524D15   IMM0524D	Ratings:	IMM05 IMM05 IMM05 IMM05 IMM05	05Syyy 4.5-9 05Dyyy 4.5-9 12Syyy 9-18 12Dyyy 9-18 24Syyy 18-36
IMM0505S05 1372   IMM0505S12 1372   IMM0505S12 1372   IMM0505S15 1355   IMM0505D12 1389   IMM0505D15 1389   IMM0512S3V3 550   IMM0512S12 678   IMM0512S12 678   IMM0512D12 686   IMM0512D15 686   IMM0512D15 686   IMM0512D15 686   IMM0524S3V3 275   IMM0524S3V3 3275   IMM0524S12 335   IMM0524S12 335   IMM0524S12 335   IMM0524D12 339   IMM0524D12 339   IMM0524D12 339   IMM0524D15   IMM0524D		Input C	urrent (mA):
IMM0505S12 1372   IMM0505S15 1355   IMM0505D12 1389   IMM0505D15 1389   IMM0512S3V3 550   IMM0512S05 678   IMM0512S12 678   IMM0512S12 678   IMM0512D12 686   IMM0512D15 686   IMM0512D15 686   IMM0512D15 686   IMM0524S05 339   IMM0524S15 335   IMM0524S15 335   IMM0524D12 339   IMM0524D12 339   IMM0524D13 339   IMM0524D15 339		IMM05	05S3V3 1100
IMM0505S15 1355   IMM0505D12 1389   IMM0505D15 1389   IMM0512S3V3 550   IMM0512S05 678   IMM0512S12 678   IMM0512S15 678   IMM0512D12 686   IMM0512D15 686   IMM0512D15 686   IMM0524S3V3 275   IMM0524S05 339   IMM0524S15 335   IMM0524S15 335   IMM0524D12 339   IMM0524D15   IMM0524D		IMM05	05S05 1372
IMM0505S15 1355   IMM0505D12 1389   IMM0505D15 1389   IMM0512S3V3 550   IMM0512S05 678   IMM0512S12 678   IMM0512S15 678   IMM0512D12 686   IMM0512D15 686   IMM0512D15 686   IMM0524S3V3 275   IMM0524S05 339   IMM0524S15 335   IMM0524S15 335   IMM0524D12 339   IMM0524D15   IMM0524D			
IMM0505D12 1389   IMM0505D15 1389   IMM0512S3V3 550   IMM0512S05 678   IMM0512S12 678   IMM0512S15 678   IMM0512D12 686   IMM0512D15 686   IMM0512D15 686   IMM0524S05 339   IMM0524S15 335   IMM0524S15 335   IMM0524D12 339   IMM0524D12 339   IMM0524D15 339   IMM0524D15 339   IMM0524D15 339   IMM052D15 339   IMM052D1			
IMM0505D15 1389   IMM0512S3V3 550   IMM0512S05 678   IMM0512S12 678   IMM0512S15 678   IMM0512D12 686   IMM0512D15 686   IMM0512D15 686   IMM0524S05 339   IMM0524S15 335   IMM0524S15 335   IMM0524D12 339   IMM0524D12 339   IMM0524D15 339   IMM0524D15 339   IMM052D15 3			
IMM0512S3V3 550 IMM0512S05 678 IMM0512S12 678 IMM0512D12 686 IMM0512D15 686 IMM0524S3V3 275 IMM0524S05 339 IMM0524S12 335 IMM0524D12 339 IMM0524D12 339 IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory: Testing location/ address:  UL Brea			
IMM0512S05 678 IMM0512S12 678 IMM0512D12 686 IMM0512D15 686 IMM0524S3V3 275 IMM0524S05 339 IMM0524S12 335 IMM0524S15 335 IMM0524D12 339 IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory: Testing location/ address:  UL Brea			
IMM0512S15 678 IMM0512D12 686 IMM0512D15 686 IMM0524S3V3 275 IMM0524S05 339 IMM0524S15 335 IMM0524D12 339 IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory: Testing location/ address:  UL Brea			
IMM0512S15 678 IMM0512D12 686 IMM0512D15 686 IMM0524S3V3 275 IMM0524S05 339 IMM0524S15 335 IMM0524D12 339 IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory: Testing location/ address:  UL Brea			
IMM0512D12 686 IMM0512D15 686 IMM0524S3V3 275 IMM0524S05 339 IMM0524S12 335 IMM0524S15 335 IMM0524D12 339 IMM0524D15 339 IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory: Testing location/ address:  UL Brea			
IMM0512D15 686 IMM0524S3V3 275 IMM0524S05 339 IMM0524S12 335 IMM0524S15 335 IMM0524D12 339 IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory: Testing location/ address:  UL Brea			
IMM0524S05 339 IMM0524S12 335 IMM0524S15 335 IMM0524D12 339 IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory: Testing location/ address:  UL Brea			
IMM0524S12 335 IMM0524S15 335 IMM0524D12 339 IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory:  Testing location/ address:  UL Brea		IMM05	24S3V3 275
IMM0524S15 335 IMM0524D12 339 IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory: Testing location/ address:  UL Brea		IMM05	24S05 339
IMM0524D12 339 IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory: Testing location/ address:  UL Brea		IMM05	24S12 335
IMM0524D15 339 Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory:  Testing location/ address:  UL Brea		IMM05	24S15 335
Output: Refer to model differences.  Testing procedure and testing location:  [X] CB Testing Laboratory:  Testing location/ address:  UL Brea		IMM05	24D12 339
Testing procedure and testing location:  [X] CB Testing Laboratory:  Testing location/ address:  UL Brea		IMM05	24D15 339
Testing procedure and testing location:  [X] CB Testing Laboratory:  Testing location/ address:  UL Brea			
[X] CB Testing Laboratory:  Testing location/ address:  UL Brea		Output	Refer to model differences.
[X] CB Testing Laboratory:  Testing location/ address:  UL Brea			
Testing location/ address:  UL Brea	Testing procedure and testing location	:	
	[X] CB Testing Laboratory:		
	Testing location/ address:		

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[] Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name, function, signature):	Rahul Baria, Project Handler	Rahul Baria
Approved by (name, function, signature):	Jonathan Chen, Project Reviewer	Jost Kan Chan
[] 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:	XP Power Limited, 401 Comm Technocentre, Lobby B, #02-	
Tested by (name, function, signature):	Alicia Chiang - Tester	See the original CBTR for signatures
Witnessed by (name, function, signature):		
Approved by (name, function, signature):	Ahmad Daoudi - Project Reviewer	See the original CBTR for signatures
Supervised by (name, function, signature):	Rahul Baria - Project Handler	See the original CBTR for signatures

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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.

Summary of compliance with National Differences

List of countries addressed: Austria, Korea, Republic of, USA, Canada, United Kingdom, Sweden

[X] The product fulfils the requirements of <u>IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012</u>

(or IEC 60601-1: 2012 reprint).

Page 5 of 148 Report No.: E321744-D1018-1/A1/C0-CB

# 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.

Page 6 of 148 Report No.: E321744-D1018-1/A1/C0-CB

GENERAL INFORMATION

Test item particulars (see also Clause 6):

Classification of Installation and Use: Building-in Device type (component/sub-assembly/ equipment/ system): Component

Intended use (Including type of patient, application location): Component DC-DC converter for use in

medical power supplies

Mode of Operation: Continuous

Supply Connection: None Accessories and detachable parts included: None Other Options Include: None

**Testing** 

Date of receipt of test item(s) ..... 2018-04-01, 2018-04-07, 2018-06-07;

N/A(A1)

Dates tests performed ..... 2018-05-15 to 2018-08-31, 2018-09-25;

N/A(A1)

Possible test case verdicts:

- test case does not apply to the test object .....: N/A

- test object does meet the requirement..... Pass (P)

N/E - test object was not evaluated for the requirement .....:

- 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 point is used as the decimal separator.

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

Not Applicable Manufacturer stating that the sample(s) submitted for evaluation

is (are) representative of the products from each factory has

been provided .....:

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

Name and address of factory (ies) ..... Motien Technology Co Ltd

9 Keji 2nd Rd Technology Industrial Park

Tainan 70955 TAIWAN

### GENERAL PRODUCT INFORMATION:

### **Report Summary**

All applicable tests according to the referenced standard(s) have been carried out.

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

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### **Product Description**

The unit is a component dc to dc Converter to be used as part of Medical Electrical Equipment, and is intended to provide one MOPP between input circuits to output circuit

### **Model Differences**

IMM05xxSyyy and IMM05xxDyyy, where xx is 05, 12, or 24 representing input voltage; and yyy is 3V3, 05, 12, or 15 representing output voltage

Model IMM05xxDyyy Series is identical to Model IMM05xxSyyy Series except it is provided with two outputs instead of one.

All models within a series are identical except for transformer windings, inductance and MOSFETs, and output ratings.

See below for Model Output Ratings @ 60°C.

IMM05XXS3V3: 3.3Vdc, 1200mA IMM05XXS05: 5 Vdc, 1000mA IMM05XXS12: 12Vdc, 416mA IMM05XXS15: 15Vdc, 333mA

IMM05XXD12: +12Vdc, 208mA; -12Vdc, 208mA IMM05XXD15: +15Vdc, 166mA; -15Vdc, 166mA

Where XX can be 05, 12, or 24, and denotes nominal input voltage ranges as follows:

05 = 4.5-9Vdc 12 = 9-18Vdc 24 = 18-36Vdc

### **Additional Information**

Project 4788728363 (Nov 2018)

This test Report should be read in conjunction with the original Report, No:

- 1. E321744-D1018-1/A0/C0-ULCB issued on 2018-09-28, with CB Certificate No. US-32504-UL, Issued on 2018-10-01.
- -This Report were deemed to amendment (technical modification), due to:
- 1. Correct electrical rating.
- 2. Typo errors in clauses .
- -No tests were deemed necessary due to no construction changed.

Marking label submitted is representative of all models in this Report.

When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

### **Technical Considerations**

• The product was investigated to the following standards:

Main Standard(s):

IEC 60601-1 Edition 3.1 (2012)

From Country Differences:

- Austria: EN 60601-1:2006/A1:2013

- Korea, Republic of: KS C IEC 60601-1

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- USA: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
- United Kingdom: BS EN 60601:2006 A1
- Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

# Additional Standards:

EN 60601-1:2006 / A1:2013 / A12:2014

- The following additional investigations were conducted: None
- The product was not investigated to the following standards or clauses: Biocompatibility, EMC, Annex Z of EN standards for compliance with the MDD
- 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
- Scope of this evaluation defers the following clauses to the be determined as part of the end product:
   Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME
- Hazard), Clause 10 (Radiation), Clause 16 (ME Systems).
- Scope of this evaluation excludes the following: Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15; Battery related clauses: 7.3.3, 15.4.3; Hand
- Control related clauses: 8.10.4; Oxygen related clauses: 11.2.2; Fluids related clauses: 11.6.2 11.6.4; Sterilization clause: 11.6.7; Biocompatibility Clause: 11.7 (ISO 10993); Motor
- related clauses: 13.2.13.3, 13.4; Heating Elements related clause: 13.2; Flammable Anaesthetic Mixtures Protection: Annex G.

### **Engineering Conditions of Acceptability**

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

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This component dc to dc converter has been judged on the basis of the required creepage and clearances for 1 MOPP based on a working voltage of 250Vrms, 354Vpk between input and output circuits at an altitude of 5000m in accordance with Standard for Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance, ANSI/AAMI ES 60601-1:2005 (R) 2012, CSA C22.2 No. 60601-1:2014 and IEC 60601-1, Edition 3.1, Sub-clause 8.9, which covers the end-use product for which the component was designed

.

The unit is a DC/DC converter and not evaluated for the separation to SUPPLY MAINS; suitable MAINS separation shall be provided during final installation

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 product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 60°C at Full Load

The output circuit has not been evaluated for connecting to Applied Parts. For end products intended to connect to Applied Parts, suitable evaluation should be considered

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 dc-to-dc converter is used within its ratings

•

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.

End product Risk Management Process to consider the need for simultaneous fault condition 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 Leakage of Liquids 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

The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.

The label has not been evaluated, the need to conduct the durability of marking and legibility of marking tests should be determined in the end product.

The product is a component for building in, the accessibility shall be determined as part of the end product investigation.

### Report Modifications

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By
2018-11-2	Project 4788728363 (Nov 2018) This test Report should be read in conjunction with the original Report, No:	Rahul Baria

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-This Report were deemed to amendment (technical modification), due to:  1. Correct electrical rating adding both of input voltage and current.  2. Typo errors in clausesClause 4.7; 8.4; 8.5.2;8.7; 8.8.4.1; 8.9.3.3; 8.10.5 No tests were deemed necessary due to no construction
changed.