Ref. Certif. No.

DK-37508-UL

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE

CERTIFICAT D'ESSAI OC

Product Produit	Medical Power Supply
Name and address of the applicant Nom et adresse du demandeur	BRIDGEPOWER CORP 964 GOSAEK-DONG GWONSEON-GU SUWON-SI, 441-813 GYEONGGI-DO KOREA
Name and address of the manufacturer Nom et adresse du fabricant	BRIDGEPOWER CORP 964 GOSAEK-DONG GWONSEON-GU SUWON-SI, 441-813 GYEONGGI-DO KOREA
Name and address of the factory Nom et adresse de l'usine Note: *When more than one factory, please report on page 2* Note: *Lorsque il y plus d'une usine, veuillez utiliser la 2ème page*	BRIDGEPOWER CORP 964 GOSAEK-DONG GWONSEON-GUSUWON-SI GYEONGGI-DO 441-813 KOREA ☒ Additional Information on page 2
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	See Page 2
Trademark (if any) Marque de fabrique (si elle existe) Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur	None
Model / Type Ref. Ref. De type	(a)ENB1020(b)(c)(d)(e)(f), BP(a)020(b)(c)(e)(f) See Page 2
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2ème page	Additionally evaluated to EN 60601-1:2006; National Differences specified in the CB Test Report. ☒ Additional Information on page 2
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	IEC 60601-1(ed.3)
As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	E302267-D17-CB-3 issued on 2014-03-10

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**

☐ UL (US), 333 Pfingsten Rd IL 60062, Northbrook, USA
☒ UL (Demko), Borupvang 5A DK-2750 Ballerup, DENMARK
☐ UL (JP), Marunouchi Trust Tower Main Building 6F, 1-8-3 Marunouchi, Chiyoda-ku, Tokyo 100-0005, JAPAN
☐ UL (CA), 7 Underwriters Road, Toronto, M1R 3B4 Ontario, CANADA

For full legal entity names see www.ul.com/ncbnames

Date: 2014-03-12

Signature:

Jan-Erik Stougaard

Ref. Certif. No.

DK-37508-UL

Model Details:
BP(a)020(b)(c)(e)(f), (a)ENB1020(b)(c)(d)(e)(f)
(a) can be A to Z for family related designs.
(b) can be S for single output in model BP(a)020 series and A to Z for design revision changes in model (a)ENB1020 series.
(c) can be 03 for 3.3Vdc, 05 for 5.0Vdc, 06 for 6.0Vdc, 07 for 7.5Vdc, 09 for 9.0Vdc, 12 for 12Vdc, 14 for 14Vdc, 15 for 15Vdc, 18 for 18Vdc, 24 for 24Vdc or 48 for 48Vdc output voltage.
(d) can be 00 thru 99 for standards output cord options ("(d)" is not provided in model BP(a)020series).
(e) can be F or N or Q or B or H or G or M or C for input plug type.
See Enclosure-Photographs for each plug-type configuration
F-Class I appliance inlet type: IEC60320-C14
Q-Class II appliance inlet type: IEC60320-C18
N-Class II appliance inlet type: IEC60320-C8
B or C-Class I & Class II direct-plug-in for North America, China, Japan and Argentina (Changeable Direct-plug-in type is only used for Class II)
H-Class I & Class II direct-plug-in for Australia (AS/NZS 3112)
G-Class I & Class II direct-plug-in for British (BS 1364)
M-Class I & Class II direct-plug-in for European (CEE /16) & Korea.
(f) can be 00 thru 99 for customer options, not related safety concerns.

Factories:
WENDENG JEIL ELECTRONICS CO LTD
DONG SHOU GUANGZHOU LU KAIFA-QU WENDENG-SHI SHANDONG
CHINA

Ratings:
Rated Input; 100-240 Vac, 50-60 Hz, , 0.5 A(0.5 A-0.3 A)
Rated Output;
3.3Vdc, 3.0A or 5Vdc, 3.0A or 5Vdc, 2.4A or 6Vdc, 2.5A or 7.5Vdc, 2.0A or 9Vdc, 2.0A or 9Vdc, 1.5A or 12Vdc, 1.5A or 14Vdc, 1.2A or 15Vdc, 1.2A or 18Vdc, 1.0A or 24Vdc, 0.75 or 48Vdc, 0.4A or 48Vdc, 0.35A.
(Rated output voltage is designated in the model name designation system).

Additional Information:
The product has been evaluated with the exception of Risk Management assessment.

Additional information (if necessary)
Information complémentaire (si nécessaire)

- ☐ UL (US), 333 Pfingsten Rd IL 60062, Northbrook, USA
- ☒ UL (Demko), Borupvang 5A DK-2750 Ballerup, DENMARK
- ☐ UL (JP), Marunouchi Trust Tower Main Building 6F, 1-8-3 Marunouchi, Chiyoda-ku, Tokyo 100-0005, JAPAN
- ☐ UL (CA), 7 Underwriters Road, Toronto, M1R 3B4 Ontario, CANADA

For full legal entity names see www.ul.com/ncbnames

Date: 2014-03-12

Signature:
Jan-Erik Storgaard

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.....:	E302267-D17-CB-3
Date of issue .....:	2014-03-10
Total number of pages.....:	279
CB Testing Laboratory.....:	UL Korea, Ltd.
Address .....:	#808, Manhatan Building, 36-2 Yeouido-Dong, Yeongdeungpo-Gu, Seoul 150-749, Korea
Applicant's name.....:	BRIDGEPOWER CORP
Address .....:	964 GOSAEK-DONG GWONSEON-GU SUWON-SI GYEONGGI-DO 441-813 KOREA
Test specification:	
Standard .....:	**IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)**
Test procedure.....:	**CB Scheme**
Non-standard test method……..:	N/A
Test Report Form No.....:	**IEC60601_1G**
Test Report Form Originator .....:	**Underwriters Laboratories Inc.**
Master TRF.....:	**Dated 2010-11**

Test item description ..... :	Medical Power Supply
Trade Mark ..... :	None
Manufacturer..... :	BRIDGEPOWER CORP 964 GOSAEK-DONG GWONSEON-GU SUWON-SI GYEONGGI-DO 441-813 KOREA

Model/Type reference..... :	BP(a)020(b)(c)(e)(f) and (a)ENB1020(b)(c)(d)(e)(f) (a) can be A to Z for family related designs. (b) can be S for single output in model BP(a)020 series and A to Z for design revision changes in model (a)ENB1020 series. (c) can be 03 for 3.3Vdc, 05 for 5.0Vdc, 06 for 6.0Vdc, 07 for 7.5Vdc, 09 for 9.0Vdc, 12 for 12Vdc, 14 for 14Vdc, 15 for 15Vdc, 18 for 18Vdc, 24 for 24Vdc or 48 for 48Vdc output voltage. (d) can be 00 thru 99 for standards output cord options ("(d)" is not provided in model BP(a)020series). (e) can be F or N or Q or B or H or G or M or C for input plug type. See Enclosure-Photographs for each plug-type configuration F-Class I appliance inlet type: IEC60320-C14 Q-Class II appliance inlet type: IEC60320-C18 N-Class II appliance inlet type: IEC60320-C8 B or C-Class I & Class II direct-plug-in for North America, China, Japan and Argentina (Changeable Direct-plug-in type is only used for Class II) H-Class I & Class II direct-plug-in for Australia (AS/NZS 3112) G-Class I & Class II direct-plug-in for British (BS 1364) M-Class I & Class II direct-plug-in for European (CEE /16)] & Korea. (f) can be 00 thru 99 for customer options, not related safety concerns.
Ratings..... :	Rated Input; 100-240 Vac, 50-60 Hz, , 0.5 A(0.5 A-0.3 A) Rated Output; 3.3Vdc, 3.0A or 5Vdc, 3.0A or 5Vdc, 2.4A or 6Vdc, 2.5A or 7.5Vdc, 2.0A or 9Vdc, 2.0A or 9Vdc, 1.5A or 12Vdc, 1.5A or 14Vdc, 1.2A or 15Vdc, 1.2A or 18Vdc, 1.0A or 24Vdc, 0.75 or 48Vdc, 0.4A or 48Vdc, 0.35A. (Rated output voltage is designated in the model name designation system).

Testing procedure and testing location:		
☒ CB Testing Laboratory:		
Testing location/ address	UL Korea, Ltd / #808, Manhatan Building, 36-2 Yeouido-Dong, Yeongdeungpo-Gu, Seoul 150-749, Korea	
☐ Associated CB Test Laboratory:		
Testing location/ address		
Tested by (name + signature)	EoJin Lim	
Approved by (+ signature)....	DongGug Cho	
☐ Testing procedure: TMP		
Tested by (name + signature)		
Approved by (+ signature)....		
Testing location/ address		
☐ Testing procedure: WMT		
Tested by (name + signature)		
Witnessed by (+ signature) ..		
Approved by (+ signature)....		
Testing location/ address		
☐ Testing procedure: SMT		
Tested by (name + signature)		
Approved by (+ signature)....		
Supervised by (+ signature)		
Testing location/ address		
☐ Testing procedure: RMT		
Tested by (name + signature)		
Approved by (+ signature)....		
Supervised by (+ signature)		
Testing location/ address		

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

- Photographs (17 pages)
- Schematics + PWB (34 pages)
- Miscellaneous (12 pages)
- Marking Plate (4 pages)

Summary of testing

Unless otherwise indicated, all tests were conducted at UL Korea, Ltd. / #808, Manhatan Building, 36-2 Yeouido-Dong, Yeongdeungpo-Gu, Seoul 150-749, Korea

Tests performed (name of test and test clause):	**Testing location:**
LEAKAGE CURRENT TEST: (IEC 60601-1, 3RD EDITION, CLAUSE 8.7)	
DIELECTRIC VOLTAGE WITHSTAND: (IEC 60601-1, 3RD EDITION, CLAUSE 8.8.3)	

Summary of compliance with National Differences

List of countries addressed: CA, CH, US

☒ The product fulfils the requirements of IEC 60601-1 Third Edition.

Copy of marking plate - Refer to Attachment titled Marking Plate for copy

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Hand-held or Portable
Device type (component/sub-assembly/ equipment/ system) ..... :	Component power supply
Intended use (Including type of patient, application location) ..... :	To supply regulated power.
Mode of operation ..... :	Continuous
Supply connection ..... :	Appliance inlet or Direct Plug-in type
Accessories and detachable parts included ..... :	None
Other options include ..... :	None
Testing	
Date of receipt of test item(s) ..... :	2014-02-25
Dates tests performed ..... :	2014-02-25
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
- test object does not meet the requirement .....:	Fail (F)
Abbreviations used in the report:	
- normal condition .....: N.C.	- single fault condition..... : S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection ..... : MOPP

General remarks:

"(see Attachment #)" refers to additional information appended to the report.

"(see appended table)" refers to a table appended to the report.

The tests results presented in this report relate only to the object tested.

This report shall not be reproduced except in full without the written approval of the testing laboratory.

List of test equipment must be kept on file and available for review.

Additional test data and/or information provided in the attachments to this report.

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

Manufacturer's Declaration per sub-clause 6.2.5 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** ☐ **Not applicable**

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

Name and address of factory (ies)..... :

BRIDGEPOWER CORP

964 GOSAEK-DONG GWONSEON-GU
SUWON-SI GYEONGGI-DO 441-813 KOREA

WENDENG JEIL ELECTRONICS CO LTD

DONG SHOU GUANGZHOU LU KAIFA-QU
WENDENG-SHI SHANDONG CHINA

General product information:

Products are component power supplies intended to be used as part of Medical Electrical Equipment. This AC Input Power Supply provides 2MOPP isolation from Primary to Secondary/Enclosure (for Class II construction) and/or 1MOPP isolation from Primary to Earth (for Class I construction). It contains the mains transformer with UL Recognized Insulation System.

This product is the AC-DC Adaptor of the switching type power supply, which electronic components are mounted on PWB and housed in plastic enclosure and provided with appliance inlet.

Testing of this AC-DC Adaptor was not considered necessary based on the results of previous investigations to IEC 60601-1 Second Edition and IEC 60950-1 Second Edition. (CBTR Ref. No. E302267-A31-CB-1, CB Test Certificate Ref. No. DK-20307)

Model Differences

The BP-series is the base model. Model ENB1020-series is identical to the base model BP-series except for the model type designations.

The below information is nomenclature detail for BP(a)020(b)(c)(e)(f) and (a)ENB1020(b)(c)(d)(e)(f):

(a) can be A to Z for family related designs.

(b) can be S for single output in model BP(a)020 series and A to Z for design revision changes in model (a)ENB1020 series.

(c) can be 03, 05, 06, 07, 09, 12, 14, 15, 18, 24 or 48 for output voltage.

(d) can be 00 thru 99 for standards output cord options ("(d)" is not provided in model BP(a)020series).

(e) can be F or N or Q or B or H or G or M or C for input plug type.

See Enclosure-Photographs for each plug-type configuration

F-Class I appliance inlet type: IEC60320-C14

Q-Class II appliance inlet type: IEC60320-C18

N-Class II appliance inlet type: IEC60320-C8

B or C-Class I & Class II direct-plug-in for North America, China, Japan and Argentina (Changeable Direct-plug-in type is only used for Class II)

H-Class I & Class II direct-plug-in for Australia (AS/NZS 3112)

G-Class I & Class II direct-plug-in for British (BS 1364)

M-Class I & Class II direct-plug-in for European (CEE /16)] & Korea.

(f) can be 00 thru 99 for customer options, not related safety concerns.

Additional Information

This report is a reissue of CBTR Ref. No.: E302267-12CA23551 and E302267-D17-CB-2, CB Test Certificate Ref. No. DK-29470-M1-UL. Based on previously conducted testing and the review of product construction, it was determined that the product continues to comply with the standard.

Technical Considerations

- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1:2005/C1:2009 (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:08 (includes National Differences for Canada), EN 60601-1:2006
- Scope of Power Supply 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 (Mechanical Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)

- Scope of Power Supply 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
  - These power supplies have been previously evaluated by UL to IEC 60601-1:1988+ A1:1991+ A2:1995 (2nd ed.), UL 60601-1: 1st ed., 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada), and EN 60601-1:1990+A1:1993+A2:1995 under CB Test Report No. E302267-A31-CB-1 and Certificate No. DK-20307, and also by UL to IEC 60950-1:2005 under CB Test Report No. E300305-A53-CB-3, and Certificate No. DK-27891-UL and DK-27891-A1-UL. All tests conducted per 2nd ed. of IEC 60601-1 and IEC 60950-1 were considered representative of the corresponding tests required by 3rd ed. of IEC 60601-1 as stated under Summary of Testing above.
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: IPX2 for Class I products only.
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product is suitable for use in the presence of a flammable anaesthetics mixture with air or oxygen or with nitrous oxide: No
- The product has been considered for Pollution Degree 2 and Overvoltage Category II.

Risk Controls/Engineering Conditions of Acceptability

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

- 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 output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
- Power supply provides the following MOPP (means of operator protection): 2 MOPP based upon a rated voltage 198 Vrms and a working voltage 600 Vpk between Primary and Secondary/Enclosure and 1 MOPP based on a rated voltage 240 Vrms between Primary and Earth.
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Marking Legibility 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 40 °C at Full Load.

- Magnetic devices (T1) employ a Class B (130°C) insulation system.
- The PWB is rated 105°C minimum.
- The products were tested on a 15 A 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.
- End product Risk Management Process to consider the need for different orientations of installation during testing.
- Power Supply tested for 48 hours Humidity Preconditioning. End product Risk Management Process to determine risk acceptability criteria.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- Temperature Test was conducted without Test Corner due to no heating elements incorporated in this power supply. 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 results of Mechanical Testing conducted.