Underwriters Laboratories (UL LLC)
Safety Certification (Manufacturing Factory) Report

Model:	DK-13991. DK-14106
Device Description:	Medical, Dental Power Supply
Applicant:	V GULDMANN A/S GRAHAM BELLS VEJ 21-23A 8200 AARHUS N DENMARK
Manufacturer:	Same as Applicant
Manufacturing Facility(ies):	FOSHAN NORATEL ELECTRIC CO LTD JUNYE RD, ZONE C OF SHISHAN INDUSTRIAL PARK, NANHAI DISTRICT, FOSHAN GUANDONG 522825 CHINA
Report No.:	E351786-D1000-1/A0/C0-(M)
Report (Re)Issue Date:	2018-2-21
Base Standard(s):	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CAN/CSA C22.2 No. 60601-1:14
Additional Standards:	IEC 60601-1-6:2010, AMD1:2013
Report Types:	This report consists of the following report types: [Yes] US Certification (UL Recognition) [Yes] CAN Certification (cUL Recognition)

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

This is the Manufacturing Factory report only, which is used as part of the factory FUS inspections.

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APPENDIX A: Enclosures

All Enclosures associated with this report are shown below.

Enclosures

Supplement - (ID)	Description
Manuals - (01)	GB Guldmann Transformer AC vers.5
Marking Label - (07)	550085_16_TransformerClass1_info
Marking Label - (08)	552621_3_TransformerClass1_box
Miscellaneous - (02)	MATERIALEBESKRIVELSE for Ulveco Transformer BB
Photographs - (01)	DK-14106
Photographs - (04)	E351786-D1000 Power Supply Exterior-1

Manuals - (01) GB Guldmann Transformer AC vers.5

Manuals - (01) GB Guldmann Transformer AC vers.5

Guldmann™

GB Guldmann Transformer AC/AC

Vers. 5.00

GB

Guldmann Transformer AC/AC

Type no.: DK-13991, DK-14100

Transformer
The Guldmann Transformer is primarily used as a power supply for charging Ceiling hoist in a ra -system.
The transformer must be connected and switched on before charging can take place. A green indicator lamp on the transformer indicates that it is connected and switched on.

Precautions

- Do not modify this equipment without authorization of the manufacture
- The transformer must not be installed where there is a risk of it being splashed with water
- If a defect of the transformer appears during use stop using the equipment and contact the Guldmann Service Team for repairs
- No part of the equipment shall be serviced when in use with a patient
- Transport of this equipment should only be undertaken after conditions described in section for Environmental conditions

Degree of protection against harmful ingress of liquids (water)
Transformer. IP20

Class I equipment: For installation with protective ground

Class II equipment: For installation without protective ground

Use of permanently installed transformer
Permanently installed transformers Class I & II, must be installed by a qualified technician or by Guldmann Service Team. The transformer is disconnected from Supply Mains by breaking the mains breaker switch. See Installation Guide. (Class II only outside US/CAN).

Environmental conditions
Operation
The products operational environment:
– Operation temperatures between 10°C and +35°C / 50°F and 95°F
– A relative air humidity of between 30% and 70%
– An air pressure of between 700 hPa and 1060 hPa
Information is illustrated by symbols on packaging

Besides temperature the same environmental conditions apply for transportation and storage
– Transport and storage temperatures between -10°C and +40°C / 14°F and 104°F
The equipment is not designed to be used at attitudes higher than 2000m above sea level

Maintenance and cleaning
The transformer is maintenance free. Clean the transformer with a damp cloth and mild hand wash detergent. Do not use strong acids, bases or alcohol to clean the transformer.
The transformer is not suitable for use in the presence of flammable mixtures.

Electronics
Power supply. . . . . 33V AC, 2.5 A
Supply voltage
Transformer US/CAN/JAP. . . 100-115V AC 50-60 Hz, 1A (T)
Transformer EU. . . . . 230V AC 50-60 Hz, 0,5A (T)

Classification

CE marking

Medical equipment with respect to electrical shock, fire and mechanical hazards only. In accordance with UL 60601-1, CAN/CSA-c22.2 No. 601.1

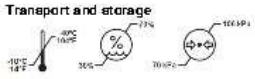
PSE marking

Class II

Read the manual before use

Must not be disposed of as standard household waste, must be recycled.

Transport and storage



V. Guldmann A/S
Graham Bells Vej 21-23A
DK-8200 Aarhus N
Tel.: +45 8741 3100
Fax +45 8741 3131
www.guldmann.com

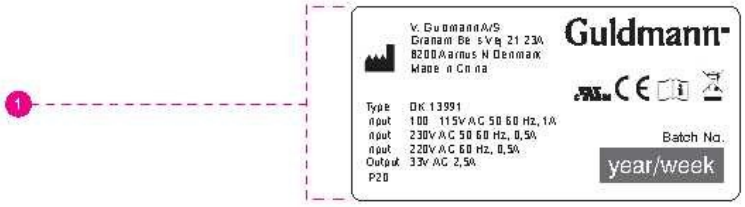
Marking Label - (07) 550085_16_TransformerClass1_info

Marking Label - (07) 550085_16_TransformerClass1_info

Rev. No	Revision note	Date	Drawing by
16.0	Label changed	26-01-2017	KLH / LE

Transformer 115V/230V
Kl. 1

Item No.
550085_16



Material
Norrs Print Tech A/S
Transparant polyester
THERMLfilm PM 200 CLEAR
TC 387 L23.

Item No. 944406
Thermo transfer ribbon
NPT RZXXXUL
Black.

Approvals acc. To
UL Standard 969
UL file: MH 27707
(CCN: PGJI2)

Size
70 x 35 mm

Font
Arial Regular

26.01.2017

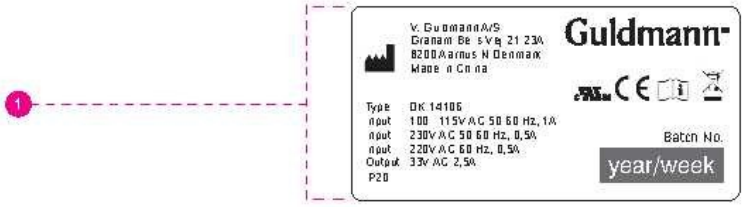
Marking Label - (08) 552621_3_TransformerClass1_box

Marking Label - (08) 552621_3_TransformerClass1_box

Rev. No	Revision note	Date	Drawing by
3.1	Label changed	20-02-2017	KLH / LE

Transformer 115/230V
Kl. 1, Metal box

Item No.
552621_3



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Thermo transfer ribbon
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Approvals acc. To
UL Standard 969
UL file: MH 27707
(CCN: PGJI2)

Size
70 x 35 mm

Font
Arial Regular

20.02.2017

Miscellaneous - (02) MATERIALEBESKRIVELSE for Ulveco Transformer BB

Miscellaneous - (02) MATERIALEBESKRIVELSE for Ulveco Transformer BB

MATERIALEBESKRIVELSE for Ulveco Transformer BB-50155 og kasse DK-13991

Core
Toroidal core made from grain oriented silicon steel.(M5, 0.30 mm thick)

Core insulation
Core insulated by taping the core with 4 layers of polyesther film
- class B. Each layer 0,05 mm thick. (UL file no. E 93687)

Primary windings
Polyestherimide enamelled copper wire.
Grade 2 - class H.
(UL file no. E 101843)

Thermal cut-off
Thermik - type S01 110°C. (UL file no. E 54236)

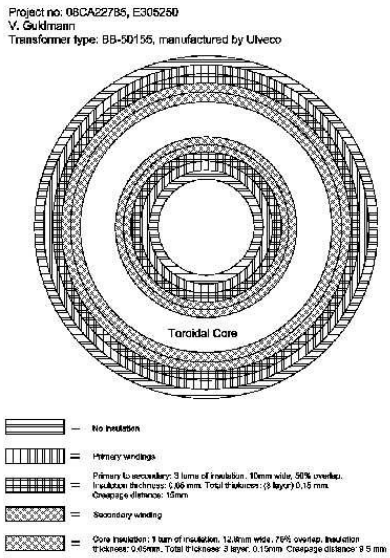
Primary insulation
6layers of polyesther film - class B. Each layer 0,05 mm thick. (UL file no. E 93687)

Reinforced insulation
Sleeving. (UL file no. E 15069)

Secondary windings
Polyestherimide enamelled copper wire.
Grade 2 - class H.
(UL file no. E 101843)

Termination
20AWG Litzer: Appliance wiring material - stranded. (UL file no. E 34722, E 140404 or E 83617)
Natvar : Sleeving (UL file no. E 15069)

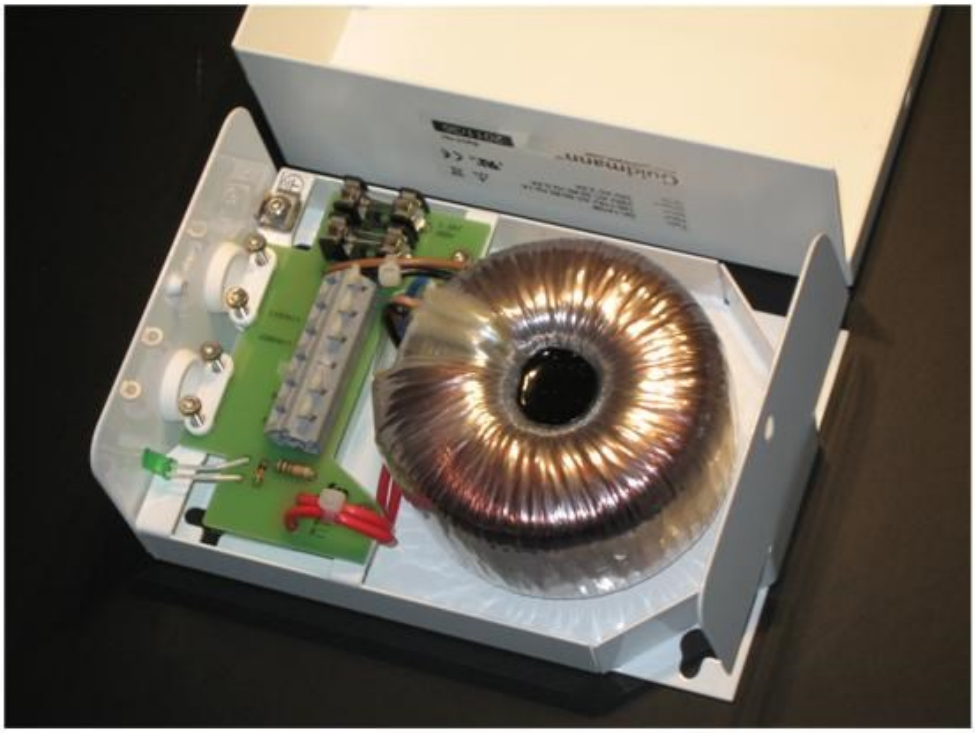
Tape
All tape used is polyesther film - Class B (UL file no. E 86214, E 20780, 63902 or E 17385 (N))



Photographs - (01) DK-14106

Photographs - (01) DK-14106

Overall view



Internal view

Photographs - (04) E351786-D1000 Power Supply Exterior-1

Photographs - (04) E351786-D1000 Power Supply Exterior-1

Power Supply, Class I

Power Supply, Internal view

APPENDIX C: Follow-Up Service Documentation

Follow-Up Service Procedure

It is important to keep UL Procedures and Test Reports up-to-date as new or revised pages are received. Correct maintenance will decrease the amount of time the UL Representative spends when visiting your facility.

UL LLC offers MyHome @UL, a dedicated website providing secure access to online tools and databases that can help simplify your compliance activities. You can customize your personal MyHome @UL page to include the content needed most, including timely information about certification updates and links to other Web sites you visit regularly. Visit http://my.home.ul.com/ to sign up today!

PAGES (in content order)	FUNCTION	HOW TO UPDATE
Authorization Page	Displays the Product Category, the type of Follow-Up Service (Type R=Reexamination / Type L=Label), the File Number and the Volume Number associated with each Applicant's, Manufacturer's and Listee's company name and address.	Replace existing page by matching the UL File Number and Volume Number. Discard the older page (refer to "Issued" or "Revised" date).
Addendum to Authorization Page*	Lists the additional names and addresses of manufacturing locations, when multiple locations exist	Replace existing page by matching the UL File Number and Volume Number. Discard the older page (refer to "Issued" or "Revised" date).
Listing Mark Data (LMD), Classification Mark Data (CMD) or Recognized Component Mark Data (RCMD) Pages* #	Used only for products covered under Type R Service. Displays the correct LMD, CMD, or RCMD Mark, the Control Number for Listed and Classified categories and additional information regarding minimum size, application, procurement, and any other optional markings, in addition to the UL Mark.	Replace existing page by matching the UL File Number and Volume Number. Discard the older page (refer to "Issued" or "Revised" date).
Multiple Listing (ML) Correlation Sheet*	Correlates product model numbers between those products made by a Manufacturer for the Basic Applicant and those supplied to another company, the Multiple Listee.	Replace, add or delete page(s) with most current "Issued" or "Revised" date.
Index*	Catalogs the contents of the Procedure by some logical means, i.e. Section Number, Report Reference Number, or Issue Date.	Replace present page by matching the UL File Number, Volume Number, Page Number and most current "Revised" date.
Appendices* # (App.)	Contains instructions for the Manufacturer and UL Representative concerning specific responsibilities and required periodic tests. May also outline tests to be conducted on samples to be forwarded to UL's facilities.	Replace present page by matching the UL File Number, Volume Number, Appendix letter (eg. App. A), Page Number and most current "Revised" date.
	Standardized Appendix Pages are the same for all manufacturers within a particular product category.	Replace present page by matching the Appendix letter (eg. App. A), Page Number and most current "Revised" date.
Follow-Up Inspection Instructions (FUII) Pages*	Contains information similar to that in the Appendices. FUII Pages are issued as part of the Procedure when a UL Standard is used in conjunction with the Procedure, and are the same for all manufacturers within a particular category.	Replace present pages by matching the Page Number and most current "Issued" or "Revised" date.
Section General* # (Sec. Gen.)	Contains description, requirements, identifications and/or specifications that are common to all products covered by the entire volume and supplements the information provided in the Description Section.	Replace present page by matching the UL File Number, Volume Number, Page Number and most current "Revised" date.
Description, or Section (Sec.)*	Contains the specific description of one or more products or systems. This includes written text supplemented by photographs, drawings, etc., as necessary, to define features that affect compliance with the applicable requirements.	Replace present page by matching the UL File Number, Volume Number, Section Number, Page Number and most current "Issued" date.

***** The above page(s) may not appear in all UL Follow-Up Service Procedures; UL's Conformity Assessment Services staff determines their inclusion.

These pages are combined in the **Generic Inspection Instructions** for International Style Reports, identified, as example by Vol. X1, X2, etc.

PLEASE NOTIFY YOUR LOCAL UL OFFICE OF ANY CHANGES IN CONTACT NAME, COMPANY NAME OR ADDRESS, SO THIS MATERIAL AND IMPORTANT INFORMATION CONTINUES TO BE DELIVERED TO YOUR FACILITY WITHOUT INTERRUPTION.

UL Authorization Page

UL File Number: E351786 Volume: D1 Issue Date: 2018-2-21

FOLLOW-UP SERVICE PROCEDURE

(TYPE R)

PRODUCT CATEGORY NAME
(MDAF2 / MDAF8)

Manufacturer: SEE ADDENDUM FOR MANUFACTURING LOCATIONS

Applicant: 421207 (Party Site)
V GULDMANN A/S
GRAHAM BELLS VEJ 21-23A
8200 AARHUS N DENMARK

Listee/Classified/ Recognized Co.: Same as Applicant (unless specified differently below)

Same as Applicant

This Follow-Up Service Procedure authorizes the above Manufacturer(s) to use the marking specified by UL LLC, or any authorized licensee of UL LLC, including the UL Contracting Party, only on products when constructed, tested and found to be in compliance with the requirements of this Follow-Up Service Procedure and in accordance with the terms of the applicable service agreement with UL Contracting Party. The UL Contracting Party for Follow-Up Services is listed on addendum to this Follow-Up Service Procedure ("UL Contracting Party"). UL Contracting Party and UL LLC are referred to jointly herein as "UL."

UL further defines responsibilities, duties and requirements for both Manufacturers and UL representatives in the document titled, "UL Mark Surveillance Requirements" that can be located at the following web-site: http://www.ul.com/fus. Manufacturers without Internet access may obtain the current version of this document from their local UL customer service representative or UL field representative. For assistance, or to obtain a paper copy of this document or the Follow-Up Service Terms referenced below, please contact UL's Customer Service at http://ul.com/aboutul/locations/, select a location and enter your request, or call the number listed for that location.

The Applicant, the specified Manufacturer(s) and any Listee/Classified/Recognized Company in this Follow-Up Service Procedure must agree to receive Follow-Up Services from UL Contracting Party. If your applicable service agreement is a Global Services Agreement ("GSA"), the Applicant, the specified Manufacturer(s) and any Listee/Classified/Recognized Company will be bound to a Service Agreement for Follow-Up Services upon the earliest by any Subscriber of use of the prescribed UL Mark, acceptance of the factory inspection, or payment of the Follow-Up Service fees which will incorporate such GSA, this Follow-Up Service Procedure and the Follow-Up Service Terms which can be accessed by clicking here: http://services.ul.com/fus-service-terms. In all other events, Follow-Up Services will be governed by and incorporate the terms of your applicable service agreement and this Follow-Up Service Procedure.

It is the responsibility of the Listee/Classified/Recognized Company to make sure that only the products meeting the aforementioned requirements bear the authorized Marks of UL LLC, or any authorized licensee of UL LLC.

This Follow-Up Service Procedure contains information for the use of the above Manufacturer(s) and representatives of UL and is not to be used for any other purpose. It is provided to the Manufacturer with the understanding that it will be returned upon request and is not to be copied in whole or in part.

This Follow-Up Service Procedure, and any subsequent revisions, is the property of UL and is not transferable. This Follow-Up Service Procedure contains confidential information for use only by the above named Manufacturer(s) and representatives of UL and is not to be used for any other purpose. It is provided to the Subscribers with the understanding that it is not to be copied, either wholly or in part unless specifically allowed, and that it will be returned to UL, upon request.

Capitalized terms used but not defined herein have the meanings set forth in the GSA and the applicable Service Terms or any other applicable UL service agreement.

UL shall not incur any obligation or liability for any loss, expense or damages, including incidental, consequential or punitive damages arising out of or in connection with the use or reliance upon this Follow-Up Service Procedure to anyone other than the above Manufacturer(s) as provided in the agreement between UL LLC or an authorized licensee of UL LLC, including UL Contracting Party, and the Manufacturer(s).

UL LLC has signed below solely in its capacity as the accredited entity to indicate that this Follow-Up Service Procedure is in compliance with the accreditation requirements.

Bruce A. Mahrenholz
Director
Conformity Assessment Programs (CPO)
UL LLC

Addendum to Authorization Page

LOCATION

Manufacturing Factory(ies) Information:

FOSHAN NORATEL ELECTRIC CO LTD
JUNYE RD, ZONE C OF SHISHAN INDUSTRIAL PARK, NANHAI DISTRICT, FOSHAN
GUANDONG 522825 CHINA

Party Site: 1251174
Subscriber No.:
Factory ID:
UL Contracting Party: UL AG

Party Site:
Subscriber No.:
Factory ID:
UL Contracting Party:

Party Site:
Subscriber No.:
Factory ID:
UL Contracting Party:

Party Site:
Subscriber No.:
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UL Contracting Party:

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Party Site:
Subscriber No.:
Factory ID:
UL Contracting Party:

UL Appendix:

GENERIC INSPECTION INSTRUCTIONS

Product Category	Product Category CCN
Medical Equipment	MDAF

These instructions consist of the following Parts:

Part	Description
AA	Instructions and Responsibilities for UL Representative
AB	Instructions for Follow-Up Tests at UL
AC	Responsibilities and Requirements for Manufacturer
AD	General Terminology
AE	General Product Construction Requirements
AF	UL Certification Marks

PART AA

INSTRUCTIONS AND DUTIES FOR UL REPRESENTATIVE

AA1.0	**UL REPRESENTATIVE'S DUTIES**
AA1.1	The UL Representative's duties include, but are not limited to: A. Examining the construction of production intended to bear the UL Mark or Marking to determine compliance with the description of the product and any other requirements expressed in this Procedure. B. Where so specified in each Test Report, forwarding samples to UL for Follow-Up tests. C. Where so specified by Part AC, inspecting the test records and facilities of the manufacturer to ensure that: 1. The proper number of samples are undergoing the required tests, and 2. The required tests are being performed correctly, and 3. The proper information is being recorded and is up-to-date, and 4. The instruments being used for the tests have been calibrated at the prescribed interval and are in good working order.

AA2.0	**PROCEDURE IN CASE OF NONCONFORMANCE**
AA2.1	Report to the manufacturer and UL LLC by means of a Variation Notice (VN) if: A. Variations in construction are found, or B. The manufacturer's method and/or frequency of testing is not as described, or C. The test records maintained by the manufacturer are not as described, or D. The manufacturer's inspection program is not being performed as described, or E. Nonconforming test results are witnessed during tests conducted specifically for the UL Representative.
AA2.2	Explain to the manufacturer that a VN is a means of communication with the manufacturer and applicant and forms a record of those items where nonconformance to the Procedure has been found. Reference is to be made to "Information for Manufacturer's Variation Notices" on the back of the VN.
AA2.3	When a product does not conform with the Procedure, require that the manufacturer: A. Remove any markings referencing UL from the product, or obliterate these markings where the marking is imprinted, die-stamped, molded, etc., or B. Suitably modify all products that do not comply with the Procedure, or C. Hold shipment pending further instructions from UL LLC D. Demonstrate that one of the conditions shown below exist and be able to provide any of the referenced information or documentation. Under the following conditions, variations from Procedure described constructions shall be noted on a Variation Notice, however, the manufacturer is not required to remove UL markings, rework the product or hold shipment. 1. A part is called out as Listed and the manufacturer or part number is not as described and the alternate part being used is Listed and all other attributes for the part are met. 2. A part is called out as a Recognized Component (R/C) and the manufacturer or part number is not as described and the alternate part being used is Recognized under the described category and all other attributes for the part are met.

	3. Internal wiring is identified by UL Style Number and the manufacturer is using (R/C) Appliance Wiring Material (AWM) with Style Numbers not referenced in the Procedure description. The manufacturer must be able to provide documentation that the voltage and temperature ratings of the alternate Style Number are equal to or greater than the ratings of the Style Numbers specified in the Procedure. AWM with Style Numbers not specified in the Procedure must be rated VW-1.
AA2.4	It is the manufacturer's responsibility to forward a copy of the Variation Notice to the Applicant.
AA2.5	If the manufacturer or Applicant question the rejection of the product, the material may be held at the point of inspection, typically at the factory, pending an appeal. The manufacturer has the right to appeal a decision with which they disagree. Provide the name of the UL engineer to whom the appeal is to be made. To resolve issues involving variations in construction, the manufacturer and Applicant may also be offered the option of contacting their New Work assignment engineer. Held shipment appeals involving Follow-Up Services issues (e.g. -improper labeling, etc.) should be directed to an appropriate staff member designated by the Reviewing Office for the product category. Should UL grant temporary authorization for the continued use of the UL Mark, such temporary authorization shall only be for the time needed to review and/or process the Procedure revisions, or as otherwise specified to cover a particular lot or production run. The manufacturer shall satisfy the UL Representative that all marks referencing UL are removed from the rejected material. Those marks referencing UL not destroyed during their removal from the product shall be turned over to the UL Representative for destruction.

AA3.0	**EXAMINATIONS TO BE WITNESSED BY UL REPRESENTATIVE**
AA3.1	**Inspection of Printed Wiring Boards and Printed Wiring Board Assemblies**
AA3.1.1	The UL Representative shall determine that the printed wiring board is as specified in the Procedure.
AA3.1.2	If the soldering operation is performed at the Original Equipment Manufacturer's factory (OEM) and the soldering temperature and dwell time are given in the Procedure, the temperature and dwell time shall also be checked to determine that they do not exceed the limits specified.
AA3.1.3	The UL Representative shall determine that the printed wiring board is as specified in the Procedure. The UL Representative then shall make a visual inspection of the printed wiring board assemblies for any mechanical damage or evidence of exposure to excessive temperatures that may have occurred during the soldering operation. The base material and the conductors shall be examined for nonconforming features as indicated below: A. Conductors, Terminal Pads, and Tabs 1. Reduction in cross-section, such as scratches, nicks, pin holes, tearing. 2. Loosening or lifting of printed wiring conductor, pad, or tab from the base material. 3. Sections missing or damaged. 4. Blistering 5. Breaks B. Base Material 1. Warping 2. Cracking 3. Charring, blistering, or other heat damage due to solder process 4. Delamination

AA3.1.4	Samples shall be selected at random as shown in Table AA1 in accordance with the size of the incoming lot. The lot is to be rejected in accordance with the fifth column of the table.
AA3.1.5	With respect to printed wiring boards using Surface Mounted Technology (SMT), if the SMT assembly process is done at temperatures and times below the soldering limits, the UL Representative will accept the boards. If the assembly process is conducted on-site with temperatures/times in excess of soldering limits or if the process is conducted off-site and the temperatures/times cannot be verified, a visual inspection will be conducted by the UL Representative in accordance with the guidelines shown above. If any instructions for SMT components are specified in the Procedure, then these SMT instructions are superseded.

TABLE AA1
PRINTED WIRING BOARD SAMPLE SELECTION

Size of incoming lot# for each type##	Initial number of samples taken	Number of nonconforming samples requiring additional samples	Additional number of samples to retest lot	Cumulative number of nonconforming samples to reject lot
1 - 500	8	1	13	2
501 – 3200	13	1	20	2
3201 - 35000	20	1	32	2
Above 35000	32	1	50	2

Notes:

\# A lot is considered to comprise all printed wiring board assemblies of the same type at the manufacturer's factory at the time of the UL Representative's visit, which have not been previously checked by the UL Representative.

A type is considered a printed wiring board assembly meeting all the following:

1. Same vendor who mounts and solders the components.
2. Same board manufacturer and type or catalog number.
3. Same size
4. Same pattern
5. Same components

AA4.0	**SAMPLE SELECTION FOR TESTS CONDUCTED AT MANUFACTURER AND UL**
AA4.1	**Standard Follow-Up Tests for Plastic Enclosures and Parts**
AA4.1.1	Each Test Report indicates the plastics enclosures or parts that may require Follow-Up Service testing. The UL Representative shall consult Table AA2 to determine which tests are required.
AA4.1.2	With respect to Table AA2, Access to Molding Operation shall be determined in accordance with the following:
	A. UL is considered to have access to the plastic molding operation if the molding takes place in the end-product assembly location and the operation complies with the requirements below.
	B. The UL Representative shall have free, unannounced, and immediate access to the factory and the storage facility during all business hours of the factory or storage facility. The UL Representative shall also have access to the records required below.
	C. The manufacturer shall mark each enclosure, cartons containing enclosures, or a tag accompanying the enclosure in a manner such that the UL Representative can trace the origin of each enclosure to a specific batch.
	D. The manufacturer shall keep records for each batch of plastic enclosures molded, in accordance with the below requirements.
	E. The records shall be thorough, so that the UL Representative may determine the composition of the enclosure. The records shall be maintained for at least six months from the date of production, and shall be accurate. All of the following items are to be covered:
	1. The records shall indicate the base material. The manufacturer may not blend resins. *Exception: The manufacturer may blend resins provided it is specifically stated in the Procedure.*
	2. The records shall include the amount of regrind used. Thermoplastic regrind shall not exceed 25 percent by weight. UL does not authorize the use of thermoset regrind. *Exception: Thermoplastic regrind may exceed 25 percent provided it is specifically stated in the Procedure and does not exceed the percent stated in the Procedure.*
	3. The composition of the enclosures shall not include recycled plastics, color concentrates, flame retardants, or mold release lubricants. *Exception: One or more of the elements indicated in 3) may be included, provided the Procedure specifically acknowledges its use.*
	F. However, if a minor discrepancy (such as a mathematical error or a bookkeeping oversight) occurs, the manufacturer shall discuss the error with the responsible individual. If necessary, the manufacturer shall correct the error on the records. To prevent recurrence of the error, the error shall be documented on a Variation Notice, and the UL Representative shall pay particular attention to this area during future inspections.
	G. If a major discrepancy appears in the records, or if the records are not complete, or UL no longer has access to the molding operation, the UL Representative shall issue a Variation Notice so that the Procedure will be modified accordingly
AA4.1.3	Where testing is required, samples are to be selected no less than once per year in accordance with each Test Report. All samples are to be handled in accordance with the requirements of this section.
AA4.1.4	Enclosure samples shall be chosen in a manner such that each enclosure material in use by the manufacturer is represented by tests no less than once over a two-year period. Enclosure materials that are used infrequently (i.e. less than once in a two year period) shall be selected whenever they are used.

TABLE AA2
FOLLOW-UP TESTING FOR PLASTIC ENCLOSURES AND PARTS

Enclosure plastic	Molding location		
	Recognized Component molder or evaluated component molder other than Recognized [d]	Not evaluated molding	
		UL has access to molding operation [a]	UL does not have access to molding operation [a]
1. Recognized Component plastic	No impact test required	Reserved (no requirement)	Reserved (no requirement)
2. Unlisted Component plastic[c]	Annual Impact test required	Annual Impact test required	Impact test required at twice annually

[a]Access to molding operation means the molding takes place in the end-product assembly location and the manufacturer follows the requirements in Access to Molding Operation in AA3.
[b]The manufacturer may elect to perform an impact test in place of the ID Tests. If the manufacturer does not elect to perform the impact test, samples are to be selected for the ID tests. See Instructions for Sample Selection, AA4.
[c]The reference to Unlisted component plastic is in regard to a component plastic used in a Listed or Recognized product which is separately investigated in accordance with applicable requirements for the end-use product, and for which no coverage has been requested or established.
[d]The reference to evaluated component molder other than Recognized is in regard to a molder of plastic fabricated parts which has been authorized by UL to mold plastic for the end-use product, but for which no Recognition has been established.

AA4.1.5	**Impact Test at Manufacturer**
AA4.1.5.1	Where indicated in Table AA2, the UL Representative shall conduct the Impact Test as part of the product inspection at the manufacturer's facility and shall determine if the manufacturer records the test data in compliance with the requirements of this document *Exception: As noted in Table AA2 footnote (d), the Impact Test shall be conducted at UL if the manufacturer does not have the ability to conduct the test.*
AA4.1.5.2	Each enclosure sample fabricated with the material specified in the Test Report shall be subjected to a single impact. The impact shall be directed onto the surface most likely to demonstrate a nonconformance when the Basis of Acceptability of AA4.1.5.3 is applied. The impact is to be produced by dropping a steel sphere 2 inches (50.8 mm) in diameter and weighing 1.18 pounds (0.536 kg mass) a height of 50.85 in. (129.2 cm). For surfaces other than the top of an enclosure the steel sphere is to be suspended by a cord and swung as a pendulum, dropping through the 50.85 in. (129.2 cm) vertical distance before striking the surface
AA4.1.5.3	Each sample shall withstand the impact of AA4.1.5.2 without being affected to the extent that: A. Uninsulated, live parts are accessible to contact, or B. The mechanical performance of the product is adversely affected so as to create a risk of injury to persons, or C. A condition is produced that can cause a risk of electric shock.
AA4.1.5.4	To determine compliance with AA4.1.5.3 (A), the UL Representative shall apply the articulate probe to verify that the probe cannot contact an uninsulated, live part. It is the manufacturer's responsibility to order and purchase the probe through UL's Corporate Standards Department, at the Northbrook Office.
AA4.1.5.5	To determine compliance with AA4.1.5.3 (B), the UL Representative shall give consideration to the functioning of safety devices and constructional features (such as thermostats, overload

	protective devices and strain relief). Cracking or denting of the enclosure shall not result in the exposure of moving parts that could cause a risk of injury to persons.
AA4.1.5.6	To determine compliance with AA4.1.5.3 (C), the product shall be subjected to a Dielectric Voltage-Withstand Test as described in AC2.3 without dielectric breakdown.
AA4.1.5.7	If the Impact Test sample produces any one of the conditions specified in AA4.1.5.3, the test is to be repeated on three previously untested samples from the same lot. The results are considered acceptable if all three samples comply with the requirements. If a nonconformance occurs on any one of the additional samples, then the lot shall be considered rejected.
AA4.1.6	**ID and Flammability Tests**
AA4.1.6.1	Samples selected in accordance with Table AA2 shall be tagged with all the following information, and the manufacturer shall forward them to the Reviewing Office: A. Material B. Manufacturer C. Model number D. Follow-Up Test(s) required E. Test parameters (if any)
AA4.2	**Standard Follow-Up Tests for Plastic Enclosures and Parts (Abnormal Operation, Mold Stress Relief Distortion and HB Flammability)**
AA4.2.1	Where specified by a Test Report, samples are to be collected once per year for these tests. All samples shall be tagged with all the following information, and the manufacturer shall forward them to the Reviewing Office:
	A. Material
	B. Manufacturer
	C. Model number
	D. Follow-Up Test(s) required
	E. Test parameters (if any)

PART AB

INSTRUCTIONS FOR FOLLOW-UP TESTS AT UL

AB1.0	**GENERAL**
AB1.1	The samples forwarded by the UL Representative shall be subjected to the tests indicated on the sample tags in accordance with any indicated test specifics (e.g. oven temperature).
AB1.2	Unless otherwise notes, all references are to the Generic Inspection Instructions.

AB1.3	**Abnormal Operation Test**
AB1.3.1	The sample shall be operated under the condition of abnormal operation indicated in the Test Report. During the test, the equipment is to rest on white tissue paper on a softwood surface and operate continuously until the ultimate results have been determined. In most cases, continuous operation for seven hours will be necessary in order to make sure that the ultimate results have been determined.
AB1.3.2	There shall be no ignition of the enclosure material, exposure of live parts, emission of flame or molten metal (except as noted below), nor glowing or flaming of the combustible material upon which the equipment is placed. Warping, shrinkage, expansion or cracking of the thermoplastic material is acceptable. Emission of flame or molten metal that occurs through regular openings provided as a part of the enclosure design and construction (not openings which occur as a result of the performance of this test) are acceptable.

TABLE AB1
TEST PARAMETERS

Test	Method	Basis for Acceptability
Impact	AA4.1.5.2	AA4.1.5.3 – AA4.1.5.7
Identification		
Qualitative Infrared Analysis (IR)	UL 746A	Compare to original spectrum in Test Report
Differential Scanning Calorimetry (DSC)	UL 746A	Compare to original thermogram in Test Report
Thermogravimetry (TGA)	UL 746A	Compare to original thermogram in Test Report
Flammability		
3/4 Inch Flame	UL 746C	UL 746C
5 Inch Flame	UL 746C	UL 746C
Mold Stress-Relief Distortion	UL746C	UL746C
HB Flammability	UL746C	UL746C
Abnormal Operation	AB1.3.1	AB1.3.2

PART AC

RESPONSIBILITIES AND REQUIREMENTS FOR MANUFACTURER

AC1.0	**MANUFACTURER'S RESPONSIBILITIES (INCLUDING BUT NOT LIMITED TO)**
AC1.1	Control of UL Mark - Restrict the use of markings that reference UL (either directly or by use of the name, an abbreviation of it, or the UL symbol or Classification Mark, or indirectly by means of agreed-upon markings that are understood to indicate acceptance by UL) to those products that are found by the manufacturer's own inspection to comply with the Procedure description. Such restrictions apply to packaging, brochures or other means of advertising that reference UL. Use of such markings is further limited by the agreements that have been executed by the subscriber and UL. Markings shall be confined to the locations authorized in these Generic Inspection Instructions or in individual Test Reports.
AC1.2	Access to Factory - During hours in which the factory is in operation, provide the UL Representative with free access to any portion of the premises where the product or components thereof are being fabricated, processed, finished or stored, and to the test area assigned for the UL Representative's use. The UL Representative shall be permitted to inspect and subject to prescribed tests, prior to shipment, any product bearing or intended to bear markings referencing UL.
AC1.3	Production-Line Tests - Conduct the tests detailed in Part AC2.0.
AC1.4	Required Records - Maintain records of test performance. The records shall include the model or catalog designation of the product, the date of production, the tests performed, number of units tested, test results and action taken on rejections. Records for test performance shall be retained for six (6) months and shall be readily available for review by the UL Representative. Exception - Records of test results need not be maintained for 100% Production-Line Tests.
AC1.5	Test Equipment and Personnel - Provide, at a convenient location, all required test equipment and facilities and any required personnel for conducting all tests that are to be performed at the factory. These shall be available when needed so that the inspection work can proceed without undue delay.
AC1.6	Test Equipment Calibration - Determine that the test equipment is functioning properly daily, and have it calibrated at least annually, or whenever it has been subject to abuse (such as being dropped or struck with an object) or its accuracy is questionable. The test equipment and instruments shall be calibrated either by the manufacturer or by an outside laboratory. In either case, it shall be calibrated by comparison with a standard that is traceable to the applicable U.S. or foreign National Standard. A letter from the outside laboratory or from an off-site manufacturer's calibration lab stating that their lab standards are directly traceable to their country's National Standard and outlining their traceability pathway is considered adequate proof of traceability. For in-house calibrations, the Standard (weight and gauge blocks, etc.) used shall be calibrated every three years, or whenever the Standard has been subject to some form of abuse that may affect the Standard's fitness for use. The Standard shall be stored to protect it from damage or deterioration per the Standard manufacturer's recommendations. Records of the calibration of the test equipment and Standard(s) shall be maintained until the next required calibration is completed and recorded, and shall be readily available for review by the UL Representative.
AC1.7	Samples for Follow-Up Testing at UL - If Part AA4.0 specifies that samples are required to be forwarded to UL for Follow-Up Testing, the manufacturer shall forward the samples selected by the UL Representative, to the specified UL Testing Laboratory, within five working days of the UL Representative's inspection visit. Packaging and shipment of the samples are the responsibility of the manufacturer.
AC1.8	Substitution of Non-Specified Plastic Materials - Non-specified plastic materials may not be substituted for Procedure described materials unless a minimum flammability rating at a minimum

	thickness is described. Before a non-specified plastic material can be used, current UL certification documentation must be checked to ensure that the plastic material has a flammability rating as specified at the thickness specified. Acceptable UL certification documentation includes: (a) the current edition of the Recognized Component Directory or Supplement; (b) the UL Online Certification Directory (http://www.ul.com/database); a copy of the plastic material company's Recognition Report; or d) a copy of the Recognition Card. The Component Recognition Report or Recognition Card may be used only if it is issued after the latest publication of the Recognized Component Directory. It is the responsibility of the manufacturer to provide the UL Representative with the above documentation. NOTE: The above does not apply to materials for which the specific manufacturer and type designation of the plastic is specified in the individual Test Reports (i.e. Enclosures).
AC1.9	Substitution of Non-Specified PWBs – Non-specified printed wiring boards may not be substituted for Procedure described materials unless a minimum flammability rating or maximum operating temperature is described. Before a non-specified printed wiring board can be used, current UL certification documentation must be checked to ensure that the printed wiring board meets the specified flammability rating, operating temperature rating, solder and dwell times, and direct support requirements. Acceptable UL certification documentation includes: (a) the current edition of the Recognized Component Directory or Supplement; (b) the UL Online Certification Directory (http://www.ul.com/database); (c) a copy of the printed wiring board company's Recognition Report; or (d) a copy of the Recognition Card. The Component Recognition Report or Recognition Card may be used only if it is issued after the latest publication of the Recognized Component Directory. It is the responsibility of the manufacturer to provide the UL Representative with the above documentation. NOTE: The above does not apply to materials for which the specific manufacturer and type designation of the plastic is specified in the individual Test Reports (i.e. Enclosures).
AC1.10	Articulate Probe - If the need for an articulate probe is identified in AA4.1.5, it is the manufacturer's responsibility to purchase the probe, and make it available for the UL Representative's use. The probe may be ordered through UL's Corporate Standards Department, at the Northbrook Office.

AC2.0	**REQUIREMENTS FOR PRODUCTION-LINE TESTS**
AC2.1	The following Production-Line Tests shall be conducted on the products covered by this Procedure. During production, the test equipment shall be checked for proper operation at least once during each shift. When the tests are not performed concurrently, it is preferred that the Grounding Continuity Test be performed before either Dielectric Voltage-Withstand Test.
AC2.2	**Production-Line Grounding Continuity Test**
AC2.2.1	General - Except as may be noted under "Exceptions" in each Test Report, the manufacturer shall subject 100 percent of production of all of the following products to a routine Production-Line Grounding Continuity Test as described in section AC2.2.3: A. Products that are provided with a grounding type power supply cord, or B. Fixed products that are for permanent connection to the branch circuit. Exception: This test is not required for permanent connection to the branch circuit by fixed wiring if the design does not employ bonding jumpers or grounding wiring to remote units.
AC2.2.2	Test Equipment - Any suitable continuity-indicating device (such as an ohmmeter, a battery and buzzer combination, or the like) may be used to determine compliance with the Grounding Continuity Test requirements.
AC2.2.3	Method - Continuity shall be determined between the grounding conductor of the attachment plug cap, and/or the designated main grounding point, and accessible dead-metal parts of the product, using the test equipment indicated above. A single test is sufficient if the accessible metal selected is conductively connected by design to all other accessible metal.
AC2.2.4	Basis for Acceptability - There shall be grounding continuity between the parts specified.
AC2.3	**Production-Line Dielectric Voltage-Withstand Test**
AC2.3.1	General - Except as may be noted under "Exceptions" in each Test Report, the manufacturer shall subject 100 percent of production of all products to a routine Production-Line Dielectric Voltage-Withstand Test as described in section AC2.3.3.
AC2.3.2	Test Equipment - The test equipment shall include a means of indicating the test potential, an audible or visual indicator of electrical breakdown, and either a manually operated reset device to restore the equipment after electrical breakdown or an automatic feature that rejects any unacceptable unit. If an ac test potential is applied, the test equipment shall also include a transformer having an essentially sinusoidal output. If the output of the test-equipment transformer is less than 500 volt-amperes, the equipment shall include a voltmeter in the output circuit to indicate the test potential directly. If the output of the test-equipment transformer is 500 volt-amperes or more, the test potential may be indicated (1) by a voltmeter in the primary circuit or in a tertiary-winding circuit, (2) by a selector switch marked to indicate the test potential, or (3), in the case of equipment having a single test-potential output, by a marking in a readily visible location to indicate the test potential. When marking is used without an indicating voltmeter, the equipment shall include a positive means, such as an indicator lamp, to indicate that the manually operated reset switch has been reset following a dielectric breakdown. Test equipment other than that described above may be used when it can be shown that UL has previously confirmed in writing that the equipment complies with the above requirements and is deemed suitable for use for this test.
AC2.3.3	Method - Each product shall withstand without electrical breakdown, as a routine production-line test, the application of an ac potential at a frequency within the range of 40-70 Hz or DC potential between the primary wiring, including connected components, and accessible dead metal parts that are likely to become energized. The test potential and duration shall be in accordance with Table AC1. The manufacturer's test conditions may be higher than those shown in Table AC1 when necessary to comply with other international product safety certifications. The product may be in a heated or unheated condition for the test. The test shall be conducted when the product is complete (fully assembled), and it is not intended that the product be unwired, modified, or disassembled for the test, unless otherwise permitted below: A. A part, such as a snap cover or a friction-fit knob, that would interfere with conducting the test need not be in place. B. The test may be conducted before final assembly if the test parameters represent that for the completed product. During the test, the primary switch is to be in the on position, both sides of the primary circuit of the product are to be connected together and to one terminal of the test equipment, and the second test-equipment terminal is to be connected to accessible dead metal. Electromagnetic interference filter capacitors connected to the primary circuit shall not be disconnected during the test.
AC2.3.4	Basis for Acceptability - All products shall withstand the applied potential without an indication of electrical breakdown.

TABLE AC1
DIELECTRIC VOLTAGE-WITHSTAND TEST CONDITIONS

Appliance Rating and Form	Test Potential (V rms)	Test Potential (V dc)	Time	Test Potential (V rms)	Test Potential (V dc)	Time
105 - 130 Volts with or without a motor rated ½ horsepower and not applied to or contacted by persons in normal use	1000	1400	1 min	1200	1700	1 sec
105 - 130 Volts and applied to or contacted by persons in the intended use or with a motor rated more than ½ horsepower	1000 + 2*U[a]	1414 + 2.828*U[a]	1 min	1200 + 2.4*U[a]	1700 + 3.4*U[a]	1 sec
210 - 600 Volts	1000 + 2*U[b]	1414 + 2.828*U[b]	1 min	1200 + 2.4*U[b]	1700 + 3.4*U[b]	1 sec
[a] - Maximum marked voltage but not less than 120 volts [b] - Maximum marked voltage but not less than 240 volts						

AC2.4	**Production-Line Patient Circuit Dielectric Voltage-Withstand Test**
AC2.4.1	General - Except as may be noted under "Exceptions" in each Test Report, the manufacturer shall subject 100 percent of production of the specified products to a routine Patient Circuit Production-Line Dielectric Voltage-Withstand Test as described in section AC2.3.3.
AC2.4.2	Test Equipment - The equipment shall be as specified in AC2.3.2.
AC2.4.3	Method - The test method shall be as specified in AC2.3.3 except: A. The potential shall be applied between the primary wiring and the applied part (patient connection). B. The test potential and duration shall be in accordance with Table AC2.
AC2.4.4	Basis for Acceptability - All products shall withstand the applied potential without an indication of electrical breakdown.

TABLE AC2
PATIENT CIRCUIT DIELECTRIC VOLTAGE-WITHSTAND TEST CONDITIONS

Appliance Rating and Form	Test Potential (V rms)	Test Potential (V dc)	Time	Test Potential (V rms)	Test Potential (V dc)	Time
Any	2500	3500	1 min	3000	4250	1 sec

PART AD

GENERAL TERMINOLOGY

AD1.0	**ABBREVIATIONS / DEFINITIONS**	
AD1.1	KAM	Known Agency Mark (Refer to Table AE3)
AD1.2	LP	Limited Power- A circuit with maximum available power of 15 or less
AD1.3	PWB	Printed wiring board
AD1.4	PRI	Primary (mains)
AD1.5	SEC	Secondary

PART AE

GENERAL PRODUCT CONSTRUCTION REQUIREMENTS

AE1.0	**CONSTRUCTION DETAILS**
AE1.1	Unless otherwise described or supplemented in individual Test Reports, the following requirements apply to all equipment included in this Procedure. It is the manufacturer's responsibility to assure the compliance of production with these requirements.
AE1.1.1	Accessories Parts and Accessories - Such items packaged with the product shall be specifically described in a Test Report.
AE1.1.2	Adapters – Three or two wire grounding type adapters shall not be furnished with the product unless specifically authorized by a Test Report.
AE1.1.3	Attachment Plugs - When a Test Report describes the power supply cord as being brazed, welded or both crimped and soldered to the plug, and the production line cannot be reviewed, the UL Representative will be required to cut open a sample of the attachment plug for confirmation.
AE1.1.4	Bonding - Except where specifically noted in a Test Report, bonding of internal dead-metal parts to the enclosure for grounding purposes shall be accomplished by a positive means such as clamping, riveting, bolting or screwed connection. The bonding connection shall reliably penetrate any nonconductive coatings such as paint or vitreous enamel.
AE1.1.5	Casualty Considerations - Except as described, or as necessary for normal operation of the equipment, there shall be no sharp edges, burrs, points, or spikes inside or outside the device that may cause injury during use or during cleaning operations.
AE1.1.6	Connectors - Connectors shall be applied so as to ensure that all bare strands are contained and insulated.
AE1.1.7	Grounding - The following guidelines shall be observed: A. Non-Detachable Cord Connected Appliance - The equipment-grounding conductor of the flexible cord: 1. Shall be connected to the grounding member of the attachment-plug cap. Note: The grounding member of the attachment-plug shall be fixed in position with respect to the cap. 2. Shall be conductively connected to all dead-metal parts of the product that are specified in the description as being connected to the grounding conductor. The grounding-conductor shall be connected by either (1) a screw or other reliable means which serves no other purpose and which is not liable to be removed during any servicing operation, or (2) a threaded grounding stud on which a closed ring connector secured to the ground conductor is the first conductor mounted and secured by a nut and split ring lockwasher. Solder alone shall not be used for securing this conductor. Note: The screw or stud and nut shall: (1) be provided with a means to penetrate nonconductive coatings, such as paint or enamel; (2) be of a corrosion-resistant metal or shall be protected against corrosion; and (3) be marked on or adjacent with a grounding symbol or the IEC417 Grounding Symbol 5019 " ⏚ ". The installation instructions shall identify the meaning of the symbol.

	B. Detachable Cord Connected Appliance - Polarization shall be maintained through the load fitting of the cord (appliance coupler) and the mating connector (appliance inlet) on the product. The load fitting shall be a three wire ANSI configuration. Exception: The load fitting need not be an ANSI configuration provided it is wired as follows (the description applies when viewing the face of the connector on the product, with the center contact down): 1. The right contact shall be connected to the grounded conductor (neutral) of the cord. 2. The center contact shall be connected to the grounding conductor of the cord. C. Permanently-Connected Products - In a permanently connected product (1) all exposed metal parts, and (2) all dead-metal parts within the enclosure, which are specified in the description as being connected (see "Bonding") to the grounding conductor, shall be conductively connected to: 1. The point of the enclosure at which the metal raceway of the power supply circuit will be connected, and 2. The equipment-grounding field-wiring terminal or lead. The equipment-grounding terminal or grounding lead shall be connected to the frame or enclosure by a positive means, such as by a bolted or screwed connection. The grounding connection shall reliably penetrate nonconductive coatings, such as paint or vitreous enamel. The grounding point shall be so located that it is unlikely that the grounding means will be removed during normal servicing. A wire-binding screw intended for the connection of an equipment-grounding conductor shall be identified by the protective earth symbol. The head shall be either hexagonal shaped or slotted, or both. A pressure wire connector intended for connection of an equipment grounding conductor shall be identified by the protective earth symbol " ⏚ ". The wire-binding screw or pressure wire connector shall be so located that it is unlikely to be removed during normal servicing of the unit.
AE1.1.8	Indicators - Indicator lights shall be clearly visible to the equipment operator.
AE1.1.9	Internal Plastic Parts - For each type of plastic material the manufacturer shall review the Recognized Component Directory and Supplement or UL Online Certification Directory (http://www.ul.com/database) in order to insure that the plastic material in question meets all the material characteristics specified (i.e. flammability rating, Relative Thermal Index (RTI), and color) at the thickness specified. Alternatively, a copy of the Plastic Manufacturer's Component Recognition Report or Recognition Card may be used as a traceability pathway only if these materials were issued after the latest publication of the Recognized Component Directory.
AE1.1.10	Internal Wiring - Conductors shall be routed away or protected from sharp edges and moving parts. Exception: LC that are reliably separated from PRI and SEC circuits need not be Recognized AWM.
AE1.1.11	Lampholder Connections - All screw shells of lampholders shall be connected to the same conductor of the supply circuit.
AE1.1.12	Loose Strands - Ends of stranded conductors shall have all strands contained to prevent contacting of, or reduction of spacing to, other live parts and dead metal. This can be accomplished by: A. Tinning B. Inserting properly into suitable wire connectors. C. Crimped connectors and/or eyelets with the crimp containing all strands

	D. Solder lugs.
AE1.1.13	Markings - Required information shall be legibly marked on the product, in the manner and minimum height specified.
AE1.1.14	Multiple Voltage - Cord-connected multiple voltage products shall be provided with an attachment plug that is suitable for the voltage for which the product is set.
AE1.1.15	Polarity - An appliance intended for permanent connection to the source of supply and having an identified terminal or lead; and an appliance employing a power supply cord with a polarized attachment plug cap (excluding 250 volt, 2-pole and 250 volt, 3-pole, 3-phase), utilizing the components indicated, shall have the components wired as follows: A. Lampholders and Receptacles - The screw shell or identified terminal or lead of a lampholder and the identified terminal or lead of a receptacle, shall be connected to the identified grounded conductor or terminal within the product. B. Switches (Single Pole) - Unless otherwise specified in the Procedure, a manual single pole switch, and an automatic control with a marked "off" position, shall not be connected to the identified grounded conductor.
AE1.1.16	Power Supply Cords A. Non-Detachable Power Supply Cord – A non-detachable power supply cord as described in each Test Report must be provided and shipped with the unit in all cases. The power supply cord and any alternatives must be described in each Test Report. Each conductor of a non-detachable power supply cord shall have only one color, except the conductor identified by a combination of green and yellow. B. Detachable Power Supply Cord – The detachable power supply cord as described in each Test Report may or may not be shipped with the unit. Follow the guidelines in Table AE1 to apply the alternatives under each of the situations described in the notes to Table AE1. Table AE1 also includes alternative detachable power supply cords that may be shipped with units intended for use outside the USA.
AE1.1.17	Printed Wiring Boards (PWBs) - PWBs shall show no burning, bubbling or other visible evidence of damage to their conductors or substrate material as a result of the fabrication process. With respect to PWBs using Surface Mounted Technology (SMT), it is acceptable if the SMT assembly process is done at temperatures and times below the soldering limits. If the SMT assembly process is conducted on-site with temperatures/times in excess of soldering limits or if the process is conducted off-site and the temperatures/times cannot be verified, a visual inspection shall be conducted by the UL Representative. The PWBs shall be inspected by the manufacturer for mechanical damage or evidence of exposure to excessive temperatures that may have occurred during the soldering operation. If any nonconforming features (defined below) are found after visual inspection, the manufacturer shall reject the lot (as defined in Table AA1). Otherwise, the use of PWBs may continue without any interruption. The base material and the conductors shall be examined for nonconforming features as indicated below. A. Conductors, Terminal Pads, and Tabs 1. Reduction in cross-section, such as scratches, nicks, pin holes, tearing. 2. Loosening or lifting of printed wiring conductor, pad, or tab from the base material. 3. Sections missing or damaged. 4. Blistering

	5. Breaks B. Base Material 1. Warping 2. Cracking 3. Charring, blistering, or other heat damage due to solder process 4. Delamination
AE1.1.18	Protection of Wiring - All wire and wire insulation in the product shall be protected from damage. This is commonly achieved by securement, segregation, and routing to keep the wire away from parts or assemblies which can damage the wire or insulation. Internal wiring that might make contact with metal parts shall be protected from sharp metal edges. This can be accomplished by rounding or deburring the metal, using a Recognized Component bushing, or through other construction features described in the Test Report. If the wiring is located where it may be in proximity to combustible material, it shall be protected by the method(s) described in the individual Test Report. Conductors shall be examined for evidence of damage. Faulty practices which can cause damage to conductors and/or insulation include: A. Improper application of crimped connectors, including but not limited to, use of crimping tool and dies not recommended by the manufacturer of the connector. B. Improper insulation removal. C. Overheating of conductor insulation because of routing or contact with hot surfaces during or after installation. D. Use of wire in which the insulation has been cut, cracked, crushed, abraded, etc. Constructions which may cause damage to conductors and/or insulation include: A. Moving parts such as rotating or reciprocating cams, shafts, and the like, as well as removable or sliding covers, hinged doors. B. Sharp edges and corners (including screw threads, burrs, points, stamped metal edges). C. Heat sources (including lamps, heating elements, etc.). D. Assemblies that clamp or squeeze wire insulation, unless described in the Test Report.

AE1.1.19	Securement of Parts - Screws or other fastenings used to mount or support small, fragile, insulating parts shall not be tight enough to cause cracking or breaking of these parts. Uninsulated live parts, components which support live parts, and dead metal parts, that are normally intended to remain stationary, shall be prevented from rotating or shifting if movement will result in twisting or stress of internal wiring or connections, or spacings being reduced below that specified in the Test Report. Similar parts that are normally intended to move or rotate shall be prevented from excessive movement if such movement will result in twisting or stress of internal wiring or connections, or spacings being reduced below that specified in the Test Report. A switch, lampholder, attachment plug receptacle, motor attachment plug cap, or other components subject to handling by the user shall be mounted securely and prevented from rotating. Exception: Based on engineering considerations certain constructions of securely mounted push button or plunger type switches, and lampholders of the type in which the lamp cannot be replaced (such as a neon pilot or indicator light in which the lamp is sealed in a non-removable jewel) may be excluded from the above. These constructions are described in the Procedure. However, in no case will nonconforming spacings be allowed. Some means commonly used to prevent rotation are: A. Lock washer. B. Matched keying of the component and its mounting. C. Two or more fasteners (screws, rivets, pins, etc.). D. Strap, clip, or pin fitted into an adjacent part. E. Physical barrier (molded boss, side of enclosure, adjacent component, etc.) that bears against the component.
AE1.1.20	Solder Connections - All solder connections shall be made mechanically secure before soldering. Some typical examples of mechanical securement are: A. Twisting wire around a solder post that has a change in dimension or restriction so unsoldered wire will not slip off post. B. Inserting wire through an opening, and bending over the free end.
AE1.1.21	Strain Relief - Strain Relief methods such as tying the supply cord into a knot or tying the ends of the cord with string shall not be used.
AE1.1.22	Usage Markings - There shall be no marking in the instruction manual, or on the carton or package that is, or could be construed to be, in conflict with or an extension of the use covered in the Test Report.

TABLE AE1
DETACHABLE POWER SUPPLY CORD REQUIREMENTS

Detachable Power Supply Cord	
Provided	Not Provided
A or B	(C and D) or (C and E)
A. The power supply cord should be as described in the Test Report.	
B. The detachable power supply cord is either: 1. Certified by one of the agencies listed in Table AE3; or 2. Comprised of cordage marked with an agency marking per Table AE3 or marked per Table AE4. The fittings are to be marked with at least one of the agencies listed in Table AE3. Units provided with detachable power supply cords, which are certified by one of the agencies listed in Table AE3 or AE4, shall be considered to be intended for use outside of the USA.	
C. A marking must be provided adjacent to the appliance coupler or at an equivalent location either to inform the user on proper selection of the power supply cord or to see the instruction manual for this information. This marking may be in the form of a tag, nonpermanent label, or product insert that is provided on or packaged with the product so that the marking is visible at the time of installation.	
D. The marking (tag, label, or product insert) or instruction manual must contain complete instructions concerning selection of the power supply cord. It shall include either Option 1, 2, or 3 as follows: 1. Reference to a power supply cord must be as a UL Listed detachable power supply cord consisting of the specific configuration of appliance coupler, the cord type, and the electrical rating of the power supply cord as described in each Test Report. Refer to Table AE2 for equivalent cord types. 2. Reference to a power supply cord may be made to a Listed field installed accessory kit containing a suitable Listed power supply cord. Authorization for use of a Listed field installed accessory kit must be included in the individual Test Reports. 3. Reference to a power supply cord may be made to a cord that is not Listed and not intended for use in the United States or Canada. In this case, the manufacturer is to supply the UL Representative with information to verify that the referenced cord is certified or similarly appropriate for use in the destination country.	
E. The reference to the power supply cord (see Note C) shall include instruction for selection of the proper power supply cord as described in Note B above.	

TABLE AE2
EQUIVALENT CORDS

Basis Cord Type	Equivalent Types
SP-2	SPE-2, SPT-2
SP-3	SPE-3, SPT-3
SV	SVE, SVO, SVOO, SVT, SVTO, SVTOO
SJ	SJE, SJO, SJOO, SJT, SJTO, SJTOO
S	SE, SO, SOO, ST, STO, STOO

TABLE AE3
CERTIFICATION MARKINGS

Country	Cert. Agency	Mark	Country	Cert. Agency	Mark
Argentina	IRAM		Ireland	NSAI	
Australia	SAA		Italy	IMQ	
Austria	OVE		Japan	JET, JQA	
Belgium	CEBEC		Netherlands	KEMA	
Canada	CSA		Norway	NEMKO	
China	CCC		Spain	AEE	
Denmark	DEMKO		Sweden	SEMKO	
Finland	FEI		Switzerland	SEV	
France	UTE		United Kingdom	ASTA	
Germany	VDE			BSI	

TABLE AE4
HAR FLEXIBLE CORDS
APPROVAL ORGANIZATIONS AND CORDAGE HARMONIZATION MARKING METHODS

Approval Organization	Printed or Embossed Harmonization Marking (May be Located On Jacket or Insulation of Internal Wiring)		Alternative Marking Utilizing Black-Red Yellow Thread (Length of color Section, mm)		
Comite Electrotechnique Belge (CEBEC)	CEBEC	<HAR>	10	30	10
Verband Deutscher Elektrotechniker (VDE) e.V. Prufstelle	<VDE>	<HAR>	30	10	10
Union technique de l'Electricite (UTE)	UTE	<HAR>	30	10	30
Instituto Italiano del Marchio di Qualita (IMQ)	IEMMEQU	<HAR>	10	30	50
British Approvals Service for Electric Cables (BASEC)	BASEC	<HAR>	10	10	30
N.V. KEMA	KEMA-KEUR	<HAR>	10	30	30
SEMKO AB Svenska Elektriska materielkontrollanstalter	SEMKO	<HAR>	10	10	50
Österreichischer Verband fur Elektrotechnik (ÖVE)	<ÖVE>	<HAR>	30	10	50
Danmarks Elektriske Materialkontroll (DEMKO)	<DEMKO>	<HAR>	30	10	30
National Standards Authority of Ireland (NSAI)	<NSAI>	<HAR>	30	30	50
Norges Elektriske Materiellkontroll (NEMKO)	NEMKO	<HAR>	10	10	70
Asociacion Electrotecnica Y Electronica Espanola (AEE)	<UNED>	<HAR>	30	10	70
Hellenic Organization for Standardization (ELOT)	ELOT	<HAR>	30	30	70
Instituto Portages da Qualidade (IPQ)	np	<HAR>	10	10	90
Schweizerischer Elektro Technischer Verein (SEV)	SEV	<HAR>	10	30	90
Elektriska Inspektoratet	SETI	<HAR>	10	30	90

PART AF
UL CERTIFICATION MARK

Product Category:	Medical Equipment
Product Category CCN:	MDAF2 / MDAF8
Product Identity:	Not Applicable for this Standard/CCN.

UL Recognition Mark:

AF1.1	Products Recognized under UL's Component Recognition Service are identified by marking elements consisting of:
AF1.1.1	The Recognized Company's identification specified in this document.
AF1.1.2	A catalog, model or other applicable product designation specified in the descriptive sections of this document.
AF1.1.3	The UL Recognized Component Mark shown below.
AF1.2	Only those components, which actually bear the Marking, should be considered as being covered under the Recognition Program. The UL Listing or Classification Mark is not authorized for use on or in connection with Recognized Components.
Recognized Component Mark	
AF2.2	Recognized only to United States safety requirements: 
AF2.3	Recognized only to Canadian safety requirements: 
AF2.4	Recognized to both U.S. and Canadian safety requirements: 
AF2.5	Minimum size of the Recognized Component Mark is not specified as long as it is legible. Minimum height of the registered symbol ® shall be 3/64 inch but may be omitted if it is out of proportion to the Recognized Component Mark or not legible to the naked eye.
AF2.6	The manufacturer may reproduce the Mark electronically. Any decision regarding the acceptability of the manufacturer's Mark reproduction will be made at the Reviewing Office.

Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CAN/CSA C22.2 No. 60601-1:14
Certification Type:	Component Recognition
CCN:	MDAF2 / MDAF8
Product:	Medical, Dental Power Supply
Model:	DK-13991. DK-14106
Rating:	DK-13991: 100-115Vac, 50-60Hz, 1A or 230Vac, 50-60Hz, 0.5A or 220Vac, 60Hz, 0.5A DK-14106: 100-115Vac, 50-60Hz, 1A or 230Vac, 50-60Hz, 0.5A or 220 Vac, 60Hz 0.5A
Applicant Name and Address:	V GULDMANN A/S GRAHAM BELLS VEJ 21-23A 8200 AARHUS N, DENMARK

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.

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

Prepared by: Sven Friis, Handler Reviewed by: Mona H. Nielsen, 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

The evaluated item was an AC/AC Power Supply for use with medical and dental equipment.
The Power Supply was supplied as a Class I version for permanent installation only, and as a Class II version for portable systems.
The Power Supply was primary intended for supplying Guldmann Hoist systems.
For Class I systems (permanent installations) The power Supply must be installed according to the Guldmann Installation Guide and must be performed by a Guldmann authorized electrician only.
The Power Supply was not tested for ingress of liquids.
The Power Supply was not suitable for use in presence of flammable gasses.
Refer to the Report Modifications for any modifications made to this report.

Model Differences

Model:
DK-13991: Class I. 100-115/230Vac, 50-60Hz. For permanent installation only, non-metal enclosure.
DK-14106: Class I. 100-115 / 230Vac, 50-60Hz. For permanent installation only, metal enclosure.

Additional Information

This report is a convertion from IEC/UL60601-1 2. ed. reports E305250-A4 and certificate DK-28738-UL, issued 2012-10-23 to IEC/ANSI 60601-1 3.1 edition

Technical Considerations

- The product was investigated to the following additional standards: IEC 60601-1-6:2010, AMD1:2013
- The following additional investigations were conducted: IEC 62366: 2007 (First Edition) + A1: 2014
- The product was not investigated to the following standards or clauses: N/A
- The following accessories were investigated for use with the product: N/A
-

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:
- • Continuity of protective earth shall be evaluated in final installation (Class I)
- • User and technical manual shall be evaluated in the end-use product.
- • Colors of mains conducter shallbe considered in installation
-

Markings and instructions	
Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Serial number or lot or batch identifier	Serial number or lot or batch identifier
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
IP Rating	IP20
Protective earth ground	 Internal mark
Operating Instructions	

Special Instructions to UL Representative

Production-Line Testing Requirements		
Test Exemptions - The following models are exempt from the indicated test		
Test	Exemption Specifics	Details
Grounding Continuity	The following models are exempt from the indicated test:	none
Dielectric Voltage Withstand	The following models are exempt from the indicated test:	none
Patient Circuit Dielectric Voltage Withstand	The following models are exempt from the indicated test:	all
Solid-State Components	The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	
Sample and Test Specifics for Follow-Up Tests at UL		
The following tests shall be conducted in accordance with the Generic Inspection Instructions		

Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
None	NA	NA	NA

8.10	**TABLE:** List of critical components				
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No.[1]	Required Mark(s) & Certificates of Conformity
Marking Label (AC-power supply)	Norris Print-Tech A/S	Clear PM-200-C, T/C-387 L-23	Pressure-sensitive unprinted label stock, Polyester film, Temp. 100°C	UL969	R/C, PGJI2
Marking label (AC-power supply) Printer/ink combination	NORRIS PRINT-TECH A/S	RZ	4,5µm, 180°C, (MH27707)	UL969	R/C, PGJI2
Enclosure	Sabic	HRA222 GG	Fire enclosure, Thickness (light gray part) min 2.0mm (dark gray part) 2.0mm, UL94V-0 Temp.100°C	UL94, UL746D	R/C, QMFZ2
Alternate Enclosure	CHiMei Corp.	PC-540	PC/ABS Fire enclosure, Thickness min 2.0mm UL94V-0 Temp.100°C	UL94	R/C, QMFZ2
Alternate enclosure (model 14106)	Guldmann	draw 552481-4 and 552482-3	Manufactured from 1.5mm painted iron sheet. Overall size 160 by 110 by 60 mm	Evaluated in this application	
Liquid tight flexible cord fitting, 2 provided	Bimed Teknik Aletler	BSSP-12	Spiral Cable Gland, PG9, Temp. 80°C	UL514	R/C, QCRV2
Alternate Liquid tight flexible cord fitting, 2 provided	Jacob	50.009PA	Spiral Cable Gland, PG9, Temp.100°C, Polyamide PA6 V-2	UL514 UL94	R/C, QCRV2
Secondary cable to rail	Interchangeable	Interchangeable	Min 2 x 18AWG conductor, 300V, Temp 105°C		RC, AVLV2
Connector in secondary AC-line	Neutrik	NC3MX / NC3FXX	3-pole cable connector, Rated 16A, Dielectric strength 1500Vdc, Temp. 80°C	UL1977, IEC 61076-2-103	R/C, ECBT2 (E135070)
Terminal block	Wago	256-506	Pwb terminal strip, 300V, 15A, 6-pole, pin spacing 7.62mm, Gage clamp, AWG 28 - 12	ANSI/UL 1059, UL486E	R/C, XCFR2
Fuse Prim 115Vac	Interchangeable	interchangeable	250V / 1AT, 5x20mm	UL248-14, IEC60127	R/C, JDYX2
Fuse Prim 230Vac	interchangeable	interchangeable	250V / 0.5AT, 5x20mm	UL248-14, IEC60127	R/C, JDYX2
Bundling straps for soldered wiring	interchangeable	interchangeable	Min 2.4 mm wide, 60 °C	UL1565	R/C, ZODZ2
Fuse holder	Schurter	OGN 0031.8201	For PWB, 5x20mm, 250Vac, 10A, UL file E39328	IEC60127-6, UL512	cUL, IZLT2
PWB	Interchangeable	Interchangeable	Min rated 105 °C, UL94V-0	UL94	R/C, ZPMV2
Transformer	Ulveco A/S	BB-50155	Toroid type, Prim. 115	Evaluated in this	

8.10	**TABLE:** List of critical components				
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No. [1]	Required Mark(s) & Certificates of Conformity
consisting of:			/ 230Vac, 50-60Hz, Sec. 33Vac, 2.5A See enclosure 7-01 and 7-02 for details	application	
Thermal cut-out in transformer	Thermik	S01 110(C	Self-resettable thermal cut-out, 110°C, 250Vac, 2,5A	UL2100	R/C, YFZW2

Supplementary information:

The (CB) Test Laboratory has verified the component information.

1) Anything specified within brackets "( )" is for reference purposes only and can be used to specify the UL Product Category CCN(s)/File Number if the component includes an UL Certification. This can be useful for the UL Follow-Up Service Inspection associated with the UL Mark; however if in brackets, should not be a required element of the UL Inspection.

---------- END OF APPENDIX C ----------