



HEADQUARTERS: 914 WEST PATAPSCO AVENUE • BALTIMORE, MARYLAND 21230 • PHONE (410) 354-3300 • FAX (410) 354-3313

Medical Power Supply Series GTM46360-****, GTM96183-*PD*-USB1C*, GTM96181-*PD***

Tested under

ANSI/ AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD 2:2021 CAN/CSA-C22.2 No. 60601-1:14 + A2:22 (R2022)

Medical electrical equipment— Part 1: General requirements for basic safety and essential performance IEC 60601-1-6 Edition 3.2 2020-07

CAN/CSA-C22.2 NO. 60601-1-6:11 + A1:15 + A2:21 (R2021)

Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

ANSI/ AAMI HA60601-1-11:2015 [Including AMD1: 2021] CSA C22.2 NO. 60601-1-11:15 (R2020) + A1:21

Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

File: E115461

MET Report: 130411 Approved: Jan. 31, 2024

Applicant:

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☐ MET Classification	☐ MET-C Classification

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Change Record

Change Number	Description	Approval Date	Project Number	Amendment Engineer	Engineer Initials
	None				



Description

Product(s) Covered:

• Power Supply, Table A

Power Supply, Tab	
Model	The symbol "*" means
GTM46360-***	The 1st "*" denotes the rated output wattage designation, which can be "01" to
	"30", with interval of 1.
	The 2nd "*" denotes the standard rated output voltage designation, it can be "3.0"
	to "5.0" with interval of 0.1Vdc.
	The 3rd "*"=-USB1A means USB A*1
	=-USB2A means USB A*2
	=-USB1C means USB Type C*1
	=-USB2C means USB Type C*2
	=-USB1A1C means USB A*1 and USB Type C*1
	The last * denote any six character = $0-9$ or A-Z or ()[] or – or blank for marketing
	purposes.
GTM96183-*PD*-USB1C*	The 1st "*" denotes the rated output wattage designation, which can be "18" or
	"36"
	The 2nd "*"= -PPS or blank,
	PPS means power supply with PPS (Programmable Power Supply) function, the
	rated output voltage can be "5.0" to "21.0" with interval of 0.1Vdc, the rated
	output maximum current can be 3.0A;
	blank means power supply without PPS (Programmable Power Supply) function,
	the rated output voltage can be "5.0" to "20.0" with interval of 0.1Vdc,
	The last * denote any six character = $0-9$ or A-Z or ()[] or – or blank for marketing
	purposes.
	The whole series output will be any one voltage / current combinations (Power
	Profiles), between 5.0V and 21V.
GTM96181-*PD***	The 1st "*" denotes the rated output wattage designation, which can be "18" or
	"36", with interval of 1.
	The 2nd "*"= -PPS or blank,
	PPS means power supply with PPS (Programmable Power Supply) function, the
	rated output voltage can be "5.0" to "21.0" with interval of 0.1Vdc, the rated
	output maximum current can be 3.0A;
	blank means power supply without PPS (Programmable Power Supply) function,
	the rated output voltage can be "5.0" to "20.0" with interval of 0.1Vdc,
	The 3rd "*" = blank means wall plug in with interchangeable blade
	=-T2 means desktop class II with C8 AC inlet
	=-T2A means desktop class II with C18 AC inlet
	=-T3 means desktop class I with C14 AC inlet
	=-T3A means desktop class I with C6 AC inlet
	The last *denote any six character = $0-9$ or A-Z or ()[] or – or blank for marketing
	purposes.
	The whole series output will be any one voltage/ current combinations (Power
	Profiles), between 5.0V and 21V.



Product Description:

The EUT is an adapter intended for using within the scope of medical electrical equipment, all
electronic components are mounted on PWB and housed in a plastics enclosure which is secured by
ultrasonic welding, output by non-detachable output wire or USB port, for indoor use only.

Model Differences:

- All the models are similar to each other except for model name, input method (wall plug or inlet), transformer model, output rating and output port (USB A, USB C). So, see table A and B for the detail.
- Table B: Model list:

Model	Output voltage range	Max current(A)	Max
	(V dc)		power(W)
GTM46360-***	3.0-5.0	6.0	30
GTM96183-*PD-USB1C*	5.0-20.0	3.0	36
GTM96181-*PD**			
GTM96183-*PD-PPS-USB1C*	5.0-21.0	3.0	36
GTM96181-*PD-PPS**			

Electrical Rating:

- GTM46360-***:
- Input:100-240V~, 50-60Hz, Max. 0.75A,
- Output: 3.0-5.0Vdc, Max. 6.0A, Max. 30W
- GTM96183-*PD*-USB1C*, GTM96181-*PD***:
- Input:100-240V~, 50-60Hz, 1.2A,
- Output: 5.0- 20.0Vdc, Max. 3.0A, Max. 36W
- GTM96183-*PD-PPS-USB1C*, GTM96181-*PD-PPS**:
- Input:100-240V~, 50-60Hz, 1.2A,
- Output: 5.0- 21.0Vdc, Max. 3.0A, Max. 36W



Engineering Considerations (Not For Field Representative's Use):

The Power Supplies, Series GTM46360-****, GTM96183-*PD*-USB1C*, GTM96181-*PD***, have been investigated in accordance with ANSI/ AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021, and CAN/CSA-C22.2 NO. 60601-1:14 + A2:22 (R2022), Medical electrical equipment— Part 1: General requirements for basic safety and essential performance; IEC 60601-1-6 Edition 3.2 2020-07 and CAN/CSA-C22.2 NO. 60601-1-6:11 + A1:15 + A2:21 (R2021) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability; ANSI/ AAMI HA60601-1-11:2015 [Including AMD1: 2021], CSA C22.2 NO. 60601-1-11:15 (R2020) + A1:21 Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical equipment with the following considerations:

1 Exceptions:

The following clauses are not evaluated in this report:

Clause 11.7 Biocompatibility, referencing ISO 10993

Clause 17 EMC, referencing IEC 60601-1-2

- 2 Scope of power supply evaluation defers the following clauses to be determined as part of the end-product evaluation:
 - Clause 7.5 Safety signs,
 - Claus 7.9 Accompany Documents,
 - Clause 9 ME hazard, except 9.1 and 9.3 are evaluated,
 - Clause 10 Radiation,
 - Clause 14 PEMS,
 - Clause 16 ME system,
- 3 Risk control/Engineering considerations for component power supply:

For power supplies with no Risk Management installed in an end-product, consideration must be given to the following:

- a) End-product Risk Management Process to include consideration the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1, F2).
- b) End-product Risk Management Process to include consideration the need for simultaneous fault condition testing.
- c) Power supply tested in 25°C, 95% R.H., 168 h. End-product Risk Management Process to include consideration the acceptability criteria.
- d) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- e) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the movement of components or conductors as part of the power supply.
- f)End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- g) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- h) End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- i)End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
- j)End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply.



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- k)End-product Risk Management Process to include consideration the acceptability of risk in conjunction to the selection of components as it pertains to the intend use, essential performance, transport, storage conditions as part of the power supply.
- This product must be installed in accordance with all codes applicable to the location of the installation and in accordance with its instructions for use.

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Description (Continued)

Note to Field Representative:

A sample of each component listed below and a purchase order for the work described below at the current hourly rate shall be submitted to:*

Eurofins E&E NA, Inc.

914 West Patapsco Avenue Baltimore, Maryland 21230-3432

for reassessment processed under job # for verification of construction against the associated drawings also listed below. The component(s) shall be subjected to an annual audit by MET for continued compliance. The annual re-verification is a client incurred expense to be assessed at the current hourly rate at the time of the test. The estimated time for re-verification is also listed below.

Figure/ Item #	Component	Controlled Document Number	Re-Verification Type	Estimated Time
27-40 /14	Transformers	TF102, TF103, TF123	Dimension - See Illustration 13-15, and Electric strength test	4 h

^{*}Alternatively: If the evaluation is performed by the MET representative's lab other than the location above or by the MET representative during the Follow-up inspection, all data shall be returned to the Baltimore office listed above for surveillance tracking under the assigned job number mentioned above.

The above inspections are a client incurred cost and will be billed at the hourly rate in place at the time of the inspection.



General Requirements

<u>Scope of Requirements:</u> The requirements contained within this section apply to all products contained within this Follow-Up Service Report File where applicable.

Definitions: (as defined or used in the context of the standard)

Term	Definitions
SELV:	Safety Extra Low Voltage
PCB:	Printed Circuit Board
Listed/Recognized Component:	A component evaluated to the applicable U.S. standards by a Nationally
	Recognized Testing Laboratory (NRTL).
Certified Component:	A component evaluated to the applicable Canadian standards by a
	Certification Organization (CO).
Listee:	Applicant

<u>Measurements</u>: All dimensions indicated in the body of this report are approximations unless otherwise indicated.

<u>Corrosion Protection:</u> All corrosive metals shall be provided with a means to protect from corrosion. Acceptable methods include painting, plating and galvanizing. Dissimilar metals shall not be employed where reliable continuity is required.

Soldered Connections: All soldered connections shall be made mechanically secure before soldering. Tack soldering is not acceptable. Acceptable forms of mechanical securement include:

- A) Lead is inserted through an eyelet or opening of a terminal block prior to soldering.
- B) Lead is inserted into a U or V shaped slot in the terminal prior to soldering.
- C) Lead is wrapped around a terminal post prior to soldering.
- D) Lead is tied to adjacent lead with wire tie-wrap near termination point.

<u>Electrical Connections:</u> All electrical connections other than soldering shall be provided with positive detent, crimp type insulated Recognized Component connectors suitable for the voltage and temperatures involved. They shall be sized for the wire and mounting terminations. Where hazardous voltage or energy is involved, all wire connections to connectors shall employ a recognized method of double securement. Where fork-type lugs are used, they shall be snap-on or up-turned lug type.

<u>Mechanical Assembly:</u> All parts shall be secured by welding, bolts/nuts with lock or star washers, or thread forming screws.

<u>Creepage and Clearances:</u> Shall be in accordance with the evaluated product standards.



General Requirements (Continued)

Where present, the following items are required.

Internal Plastics: Shall be a Recognized/Certified Component, Plastic, rated minimum HB/5VA.

PCB: Shall be a Recognized Component, rated minimum 94V-2 and 130°C.

<u>Tubing and Sleeving:</u> Shall be a Listed/Recognized/Certified Component, rated minimum 300V, 75°C minimum, VW-1, unless otherwise noted.

<u>Wire Connectors:</u> (Various crimp-type) Shall be Listed/Recognized/Certified Components sized for the wire and mounting terminations. Both the wire insulation and the conductor shall be crimped.

<u>Fuseholder</u>: Operator accessible fuseholders, when provided, are connected to the ungrounded conductor(s) of the primary circuit.

Internal Wiring: All internal wiring and connections are properly jacketed or enclosed within the equipment. Wiring is routed and secured to reduce the possibility of stress being transmitted to electrical connections, as necessary. All internal conductors in the secondary circuits are routed away from primary circuit conductors and from uninsulated live parts. There is no internal wiring subject to contact by the user when the product is employed as intended. The internal wiring is acceptable for conditions of service to which it will be subjected. Internal conductors consist of Recognized Component AWM insulated individual conductors; sized in accordance with the National Electric code and Canadian Electrical code, as may be applicable for the current expected in the conductor, rated 300V, 80°C, 24-18AWG.

<u>Interconnecting Cords and Cables</u>: Flexible telecommunication cord and cable assemblies employed for interconnection between components are to be rated for and comply with temperatures, exposure to oil or grease and other conditions of service within the environment the product is to be utilized.

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Markings

Etching, molding, die-stamping, silk-screening, stamped-, or etched-metal labels secured by rivets or screws are considered permanent. Recognized/Certified Component, Marking and Labeling Systems, and/or labels tested and deemed suitable for the surface to which it is applied is also considered permanent. Per the Canadian Electrical Code described in CSA C22.0 General Requirements, Canadian product certification requires warning/cautionary markings in both English and French languages. It is the Applicant's responsibility to provide the listed Bilingual Markings shown below in accordance with the Canadian regulatory requirements. Each product is to be permanently marked with the following information:

- a. The MET Mark (refer to MET Applicant Contract), with the applicant/listee name or alternate listee name as identified within this report, trade name or trade mark, product model number, and a date of manufacture or serial number. If the date of manufacture is in a code, it shall not repeat in less than 10 years and it shall not require reference to the manufacturer's records to determine when the product was manufactured.
- Method of applying the MET Mark: b.

Direct Imprinting

Purchasing Labels from MET Laboratories, Inc.

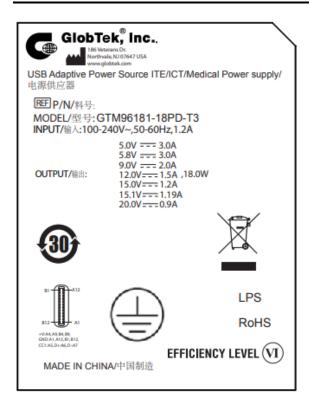
Approved MET Mark:

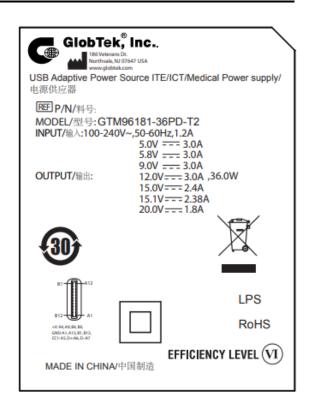


Comply with **ANSI AAMI ES 60601-1** IEC 60601-1-6 ANSI AAMI HA 60601-1-11 CAN/CSA-C22.2 NO. 60601-1 CAN/CSA-C22.2 NO. 60601-1-6 CAN/CSA-C22.2 NO. 60601-1-11

For Mains Connected Equipment, a rating label adjacent to the inlet connector identifying c. the voltage, current or power, frequency for the equipment.

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(Class I model) (Class II model)



Manual/Service Instructions

- Operations and Service instructions are provided with the equipment.
- See illustration 1 to 12.





Alternate Listee Information

Alternate listees and product names or model numbers: None



Applicant's Responsibilities

Product Modifications:

Minor product modifications by the manufacturer may be allowed using the following guidelines:

1. Components identified in this report as "Listed, Recognized, or Certified" and **NOT** identified with a manufacturer name or part number may be exchanged with an alternate "Listed, Recognized, or Certified" component of equivalent value.

Example: Appliance Inlet Connector - Listed/Certified Component, IEC 320 style male connector, rated 250 volts and 20 amperes. Mechanically secured to the front panel with screws and locking washers.

- This inlet connector may be replaced with any Listed/Certified inlet connector with the same ratings as stated and where mechanical securement is maintained.
- 2. Components identified by a manufacturer name, part number, or with specific comments, (such as AC only, indoor use only, approved for use in this product only), may **NOT** be replaced or modified without prior approval from MET Laboratories.

Example: Circuit Breaker - Recognized/Certified Component, ABCD Co. P/N XYZ123, rated 250 volts maximum, 50/60 Hz, 25 full-load amperes, 31.3 trip amperes. Toggle handle marked with IEC on/off symbols. Mechanically secured to the front panel with screws and locking washers.

• This circuit breaker can **NOT** be modified or changed without prior approval by MET Laboratories, Inc.



Applicant's Responsibilities (Continued)

Project Amendments:

For any changes related to product construction, manufacturing locations, if the product is intended to be marketed/sold under an alternate name or model number than that originally listed, or any issues which would require notification or change in the status of this file, please complete the form and return to Eurofins E&E NA following the instructions provided on the form.

For your convenience a Project Amendment Request (PAR) form is available for download at http://corp.metlabs.com/safetyreq/ Alternatively, please provide it to your local Eurofins office or Eurofins Partner Representative.

If you are terminating or temporarily suspending production of this product for an extended period, please send a letter on company letterhead to:

Eurofins E&E NA, Inc.
Attn: Follow Up Services Department
914 West Patapsco Avenue
Baltimore, Maryland 21230
USA

Fax: (410) 354-3313



Applicant's Responsibilities (Continued)

Manufacturing and Production-Line Tests and Documentation performed by Manufacturer.

All certified products are required to be subjected to production line testing as indicated below:

<u>Dielectric Voltage-Withstand Test:</u>

Each complete end product shall be capable of withstanding, without electrical breakdown, the application of a continuous sinusoidal or direct current voltage between uninsulated live parts and accessible dead metal parts that are likely to become energized in accordance with the following method.

Circuit Rating	Component Tested	Circuit Tested	Voltage (VAC)	Voltage (VDC)	Time (sec)
100 to 240 V	Main unit	Primary circuit to output port	4000		1
100 to 240 V	Main unit	Primary circuit to enclosure	4000		1
100 to 240 V	Main unit	Primary circuit to Earthing for Class I models	1500		1

Grounding Continuity Test:

Each complete product shall be tested to determine grounding continuity between the grounding pin or terminal of the attachment plug and the accessible dead metal parts that are likely to become energized. The grounding contact of each receptacle, and other means for grounding on the load side, shall be included in this test. Compliance is to be determined by any appropriate device, such as an ohmmeter, or a battery and buzzer combination, applied between the points under test.

Documentation:

The manufacturer is required to record the production line test results. The data recorded is to include the type of test, date of test, serial number of the product, indications of pass, fail, or retest, test equipment utilized, calibration date of test equipment utilized, and the initials or signature of the test technician. Test records shall be required to be maintained from factory follow-up audit to factory follow-up audit and must be available for the inspectors' review. Records may be in the form of travelers, logs, computer files, or other such suitable documentation method.



Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
1,6,11,	Plastic enclosure	SABIC JAPAN L L C	945	V-0, 120°C, Min. thickness: 2.0mm	UL 94	UL/CSA Listed (E207780)	Fixed by ultrasonic welding
15,19/	Alternative	SABIC INNOVATIVE PLASTICS B V	945, CX7211	V-0, 90°C, Min. thickness: 2.0mm	UL 94	UL/CSA Listed (E45329)	
	AC inlet for Class I models (C6 type)	LECI Electronics Co., Ltd.	DB-6	2.5A, 250Vac Standard sheet: C6	UL 60320-1	UL/CSA Listed (E302229)	Soldered on PCB and secured by enclosure
-/2	Alternative	Rich Bay Co., Ltd.	R-30790, R-307	2.5A, 250Vac Standard sheet: C6	UL 60320-1	UL/CSA Listed (E184638)	enciosare
	Alternative	TECX-UNIONS Technology Corporation	TU-333 series	2.5A, 250Vac Standard sheet: C6	UL 60320-1	UL/CSA Recognized (E220004)	
	AC inlet for Class I models (C14 type)	LECI Electronics Co., Ltd.	DB-14	10A, 250Vac Standard sheet: C14	UL 60320-1	UL/CSA Recognized (E302229)	Soldered on PCB and secured by enclosure
-/3	Alternative	Rich Bay Co., Ltd.	R-301SN	10A, 250Vac Standard sheet: C14	UL 60320-1	UL/CSA recognized (E184638)	Chelosure
	Alternative	TECX-UNIONS Technology Corporation	TU-301-S, TU-301-SP	10A, 250Vac Standard sheet: C14	UL 60320-1	UL/CSA Recognized (E220004)	
	Appliance inlet for Class II model (C8 type)	LECI Electronics Co., Ltd.	DB-8	2.5A, 250Vac Standard sheet: C8	UL 60320-1	UL/CSA Recognized (E302229)	Soldered on PCB and secured by enclosure
-/4	Alternative	Rich Bay Co., Ltd.	R- 201SN90	2.5A, 250Vac Standard sheet: C8	UL 60320-1	UL/CSA Recognized (E184638)	
	Alternative	Sun Fair Electric Wire & Cable (HK)Co. Ltd.	S-01	2.5A, 250Vac Standard sheet: C8	UL 498	UL/CSA Recognized (E226643)	
	Alternative	TECX-UNIONS Technology Corporation	SO-222 series	2.5A, 250Vac Standard sheet: C8	UL 60320-1	UL/CSA Recognized (E220004)	



Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
-/5	Appliance inlet for Class II model (C18 type)	Rong Feng Industrial Co., Ltd	SS-120	10A, 250V	UL 60320-1	UL/CSA Recognized (E102641)	Soldered on PCB and secured by enclosure
	Alt.	HCR ELECTRONICS CO., LTD	SK05	10A, 250V	UL 60320-1	UL/CSA Recognized (E344254)	
	PCB	SHUANG MING INDUSTRY CO LTD	T005V0, T015V0, T016V0	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized (E78017)	Secured by enclosure
	Alternative	GUANGDE BOYA XINXIANG ELECTRONIC TECHNOLOGY CO LTD	BY-1	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized (E475783)	
5,10, 14,18,	Alternative	JIANGXI ZHONG XIN HUA ELECTRONICS INDUSTRY CO LTD	ZXH-2	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized (E331298)	
22, /6	Alternative	SHENZHEN JIA LI CHUANG TECHNOLOGY DEVELOPMENT CO LTD	JLC-1	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized (E479892)	
	Alternative	SUZHOU CITY YILIHUA LCTRONICS CO LTD	YLH-2	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized (E251781)	
	Alternative	SHENZHEN TONGCHUANGXI N ELECTRONICS CO LTD	TCX	Min. V-0, min 1.6 mm thickness, 130°C	UL 796 UL 94	UL/CSA Recognized (E250336)	
3,9,13	Fuse (F1, F2) (F2 is optional for Class II models)	Suzhou Walter Electronic Co., Ltd.	2010	T2A, 250V	ANSI/UL 248-1, CSA- C22.2 No. 248.1	UL/CSA Recognized (E56092)	Soldered on PCB
/7	Alternative	Conquer Electronics Co., Ltd.	MST, MET	T2A, 250V	ANSI/UL 248-1, CSA- C22.2 No. 248.1	UL/CSA Recognized (E82636)	
4,9,13 /8	Y1 Capacitor (CY1, CY2) (optional)	SUCCESS ELECTRONICS CO LTD	SE	250Vac, 125°C, Max. 1500pF	ANSI/UL60 384-14	UL/CSA Recognized (E114280)	Soldered on PCB



Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
	Alternative	SUCCESS ELECTRONICS CO LTD	SB	250Vac, 125°C, Max. 1500pF	ANSI/UL60 384-14	UL/CSA Recognized (E114280)	
	Alternative	Shantou High-New Technology Dev. Zone Songtian Enterprise Co., Ltd.	CD, CE	250Vac, 125°C, Max. 1500pF	ANSI/UL60 384-14	UL/CSA Recognized (E208107)	
	Alternative	Haohua Electronic Co.	CT7	250Vac, 125°C, Max. 1500pF	ANSI/UL60 384-14	UL/CSA Recognized (E233106)	
	Alternative	TDK CORP	CD	250Vac, 125°C, Max. 1500pF	ANSI/UL60 384-14	UL/CSA Recognized (E37861)	
	X capacitor (CX1) (optional)	Shantou High-New Technology Dev.Zone Songtian	MPX	X2, AC275V, 110°C Max. 0.33μF	ANSI/UL60 384-14	UL/CSA Recognized (E208107)	Soldered on PCB
	Alternative	Enterprise Co., Ltd.	MPK	X1, AC330V, 110°C Max. 0.33μF	ANSI/UL60 384-14		
	Alternative		CD	X1, AC400V, 125°C Max. 0.33μF	ANSI/UL60 384-14		
4,9,13	Alternative		CE	X1, AC400V, 125°C Max. 0.33µF	ANSI/UL60 384-14		
/9	Alternative	Cheng Tung Industrial Co., Ltd.	CTX	X1 or X2, AC310V, 110 °C Max. 0.33μF,	ANSI/UL60 384-14	UL/CSA Recognized (E193049)	
	Alternative	Ultra Tech Xiphi Enterprise Co. Ltd.	HQX	X2, AC275V, 110 °C Max. 0.33μF,	ANSI/UL60 384-14	UL/CSA Recognized (E183780)	
	Alternative	Dain Electronics Co., Ltd.	MPX, MEX, NPX	X1 or X2, AC275V, 110 °C Max. 0.33μF,	ANSI/UL60 384-14	UL/CSA Recognized (E147776)	
	Alternative	HUA JUNG COMPONENTS CO LTD	MKP	X2, AC275V, 110 °C Max. 0.33μF,	ANSI/UL60 384-14	UL/CSA Recognized (E149075)	
4,9,13	Optocoupler (U4)	Everlight Electronics Co., Ltd.	EL1019	Ext. Cr & Cl: ≥8.0 mm; In ≥0.4 mm 110°C	UL 1577	UL/CSA Recognized (E214129)	Soldered on PCB
/10	Alternative	LITE-ON Technology Corporation	LTV-1009	Ext. Cr & Cl: ≥8.0 mm; In ≥0.4 mm 110°C	UL 1577	UL/CSA Recognized (E113898)	



Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
	Alternative	VISHAY Semiconductor GmbH	TCLT1019, VOL618A	Ext. Cr & Cl: ≥8.0 mm; In ≥0.4 mm 110°C	UL 1577	UL/CSA Recognized (E76222)	
	Varistor (MOV1) (optional)	Thinking Electronic Industrial Co., Ltd.	TVR10471, TVR14471, TFV10S47 1K, TVR10621	300Vac, coating, Min. V-0, min. 85 °C, 6KV/3KA, pulse test passed	UL 1449	UL/CSA Recognized (E314979)	Soldered on PCB
	Alternative	Thinking Electronic Industrial Co., Ltd.	TVR10471 -M	300Vac, coating, Min. V-0, min. 125 °C, 6KV/3KA, pulse test passed	UL 1449	UL/CSA Recognized (E314979)	
4,9,13 /11	Alternative	Thinking Electronic Industrial Co., Ltd.	TVT14471	300Vac, coating, Min. V-0, min. 105 °C, 6KV/3KA, pulse test passed	UL 1449	UL/CSA Recognized (E314979)	
	Alternative	XIAMEN SET ELECTRONICS CO LTD	TFV8S471 K TFV10S47 1K	300Vac, coating, Min. V-0, min. 125 °C, 6KV/3KA, pulse test passed	UL 1449	UL/CSA Recognized (E322662)	
	Alternative	SHANTOU HIGH- NEW TECHNOLOGY DEVELOPMNT ZONE SONGTIAN ENTERPRISE CO LTD	10D471K, 10D621K	300Vac, coating, Min. V-0, min. 125 °C, 6KV/3KA, pulse test passed	UL 1449	UL/CSA Recognized (E330837)	
	Alternative	Guangdong Huiwan Electronics Technology Co Ltd	V-471K- 10D, V- 471K-10E, V-471K- 14D, V- 471K-14E	300Vac, coating, Min. V-0, min. 85 °C, 6KV/3KA, pulse test passed	UL 1449	UL/CSA Recognized (E480104)	
9 /12	Bonding wire for Class I models	ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD	1015, 1007, 1185	Min. 18AWG, Min. 300V, Min. 80°C	UL 758	UL/CSA Recognized (E333601)	Soldered and fixed by glue in addition on PCB
	Alternative	Various	1015, 1007, 1185	Min. 18AWG, Min. 300V, Min. 80°C	UL 758	UL/CSA Recognized	
6,11, 12,15 /13	Output cord	KUNSHAN NEW ZHICHENG	1185, 2464,	Min. 20AWG, min. 300Vac,	UL 758	UL/CSA Recognized (E237831)	Soldered on PCB and fixed



Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
		ELECTRONICS TECHNOLOGIES CO LTD	2468, 1015	min. 80°C			by enclosure
	Alt.	ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD	SPT-1, SPT-2	Min. 20AWG, min. 300Vac, min. 80°C	UL 62	UL/CSA Recognized (E333536)	
	Alt.	Various	1185, 2464, 2468, 1015	Min. 20AWG, min. 300Vac, min. 80°C	UL 758 or UL 62	UL/CSA Recognized	
	Transformer (T1)	GlobTek/ SHAN DONG BOAM ELECTRIC CO LTD / WUXI HAOPUWEI ELECTRONICS CO., LTD	TF103 for GTM46360 series TF102 for GTM96181 series TF123 for GTM96183 series	Class B	AAMI ES 60601-1 CSA C22.2 No. 60601-1	Unlisted component	Soldered on PCB
	-Insulation system	GLOBTEK INC	GTX-130- TM	Class 130(B)	UL 1446	UL/CSA Recognized (E243347)	Fixed inside transform
	Alternative	SHAN DONG BOAM ELECTRIC CO LTD	BOAM-01	Class 130(B)	UL 1446	UL/CSA Recognized (E252329)	er
27-40 /14	Alternative	WUXI HAOPUWEI ELECTRONICS CO LTD	ZT-130	Class 130(B)	UL 1446	UL/CSA Recognized (E315275)	
	-Primary winding	WUXI JUFENG COMPOUND LINE CO LTD	2UEWB	MW75#, 130oC	UL 1446	UL/CSA Recognized (E206882)	Fixed inside transform
	Alternative	JIANGSU DARTONG M & E CO LTD	UEW	MW 75-C, 130oC	UL 1446	UL/CSA Recognized (E237377)	er
	Alternative	SHANDONG SAINT ELECTRIC CO LTD	UEW/130	MW75#, 130oC	UL 1446	UL/CSA Recognized (E194410)	
	Alternative	NINGBO JINTIAN NEW MATERIAL CO LTD	2UEW	MW 79#, 155oC	UL 1446	UL/CSA Recognized (E227047)	
	-Triple- insulated	GREAT LEOFLON	TRW(B)	Min.130°C	UL 2353	UL/CSA Recognized	Fixed inside



Figure					Standard		
/ item	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	(Edition /	Mark(s) of Conformity	Secured Method
No.			Model		year)	•	
	wire (Secondary)	INDUSTRIAL CO LTD				(E211989)	transform er
	Alternative	FURUKAWA ELECTRIC CO LTD	TEX-E	Min.130°C	UL 2353	UL/CSA Recognized (E206440)	
	Alternative	HOI LUEN ELECTRICAL MFR CO LTD	THL-F-xx, THLF-SB- xx	Min.130°C	UL 2353	UL/CSA Recognized (E257525)	
	-Bobbin	CHANG CHUN PLASTICS CO LTD	T375J, T375HF	V-0, 150°C, thickness 0.45 mm min.	UL 94 UL 746 A/B/C/D	UL/CSA Recognized (E59481)	Fixed inside transform er
	Alternative	SUMITOMO BAKELITE CO LTD	PM-9820, PM-9630	V-0, 140°C, thickness 0.74 mm min.	UL 94 UL 746 A/B/C/D	UL/CSA Recognized (E41429)	Ci
	Alternative	CHUANG CHUN PLASTICS CO LTD	4130	V-0, 150°C, thickness 0.45 mm min.	UL 94 UL 746 A/B/C/D	UL/CSA Recognized (E59481)	
	-Insulating tape	3M COMPANY	1350F-1, 1350T-1, 44	Min.130°C	UL 510	UL/CSA Recognized (E17385)	Fixed on winding and core
	Alternative	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ, CT, WF	Min.130°C	UL 510	UL/CSA Recognized (E165111)	
	Alternative	HUIZHOU YAHUA ELECTRONIC TECHNOLOGY CO LTD	CT	Min.130°C	UL 510	UL/CSA Recognized (E495875)	
	-PTFE tubing	Great Holding Industrial Co Ltd	TFT, TFS	Min. 300V, 200°C	UL 224	UL/CSA Recognized (E156256)	
4,9,13 /15	Alternative	Shenzhen Woer Heat-Shrinkable Material Co Ltd	WF	600V, 200°C	UL 224	UL/CSA Recognized (E203950)	
	Alternative	Changyuan Electronics (Shenzhen) Co Ltd	CB-TT-T, CB-TT-S	Min. 300V, 200°C	UL 224	UL/CSA Recognized (E180908)	
4,9,13 /16	Insulating tube for earthing wire	SHENZHEN WOER HEAT- SHRINKABLE MATERIAL CO LTD	RSFR, RSFR-H, RSFR-HPF	600V, 125°C	UL 224	UL/CSA Recognized (E203950)	Fixed on bonding wire
4,9,13 /17	Tape for	JINGJIANG YAHUA PRESSURE	PZ, CT	Min.130°C	UL 510A	UL/CSA Recognized	



Figure / item No.	Object/ Parts No.	Manufacturer/Trade mark	Type/ Model	Technical Data	Standard (Edition / year)	Mark(s) of Conformity	Secured Method
	HS1	SENSITIVE GLUE CO LTD				(E165111)	
	Alternative	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX*	Min.130°C	UL 510A	UL/CSA Recognized (E246820)	
	Thermal conductive pad	Suzhou Springgrass Electronic Technology Co., LTD	HRTP- M16	V-0	UL 746	UL/CSA Recognized (E528141)	Sticked to metal
4,9,13 /18	Alternative	SUZHOU HUIMEI PACKAGING PRODUCTS CO LTD	HM-300	V-0	UL 746	UL/CSA Recognized (E516470)	
	Alternative	PIONEER MATERIAL PRECISION TECH	PMP-P-300	V-0	UL 746	UL/CSA Recognized (E153203)	
/19	Marking plate	GlobTek		Permanently secured Engraving or Silkscreen or Laser printing	UL 60601-1	Tested with equipment	Sticked to enclosure surface

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Critical Drawings

Title:	Drawing No.:	Rev. Level:	Date:
Transformer construction TF102	Illustration 13	A.1	2021-12-29
Transformer construction TF103	Illustration 14	A.1	22-08-23
Transformer construction TF123	Illustration 15	A.1	2022-01-11
Circuit diagram for series GTM46300****	Illustration 16	C	2022-08-24
Circuit diagram for series GTM96183-*PD*- USB1C*, GTM96181-*PD***	Illustration 17	Е	2022-08-23
PCB layout for series GTM46300**** with USB2C / USB1A1C	Illustration 18	REV 1	2022-10-28
PCB layout for series GTM46300**** with USB2A / USB1A	Illustration 19	REV 3	2023-06-15
PCB layout for series GTM96181-*PD***	Illustration 20	REV 4	2022-11-10
PCB layout for series GTM96183-*PD*- USB1C*	Illustration 21	REV 4	2022-11-10



Figures

Figure 1.



Figure 2.

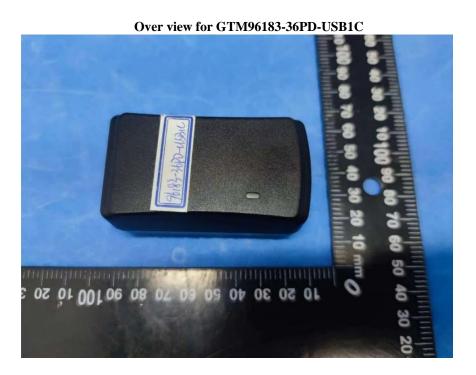




Figure 3.





Figure 4.

PCB of GTM96183-36PD-USB1C







Figure 5.

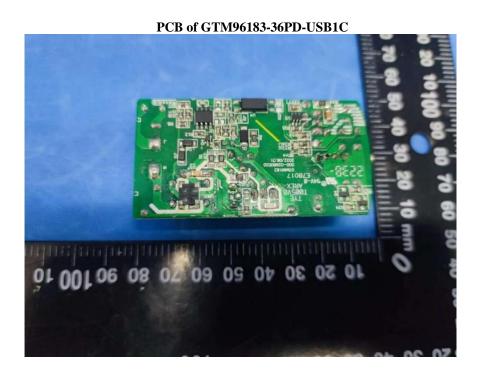


Figure 6.





Figure 7.



Figure 8.





Figure 9.





Figure 10.

PCB of GTM96181-36PD-T3





Figure 11.



Figure 12.







Figure 13.





Figure 14.

PCB of GTM96181-36PD-T2





Figure 15.



Figure 16.





Figure 17.





Figure 18.

External view of GTM96181-36PD







Figure 19.

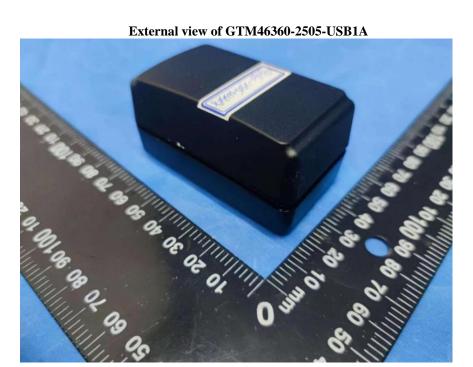


Figure 20.

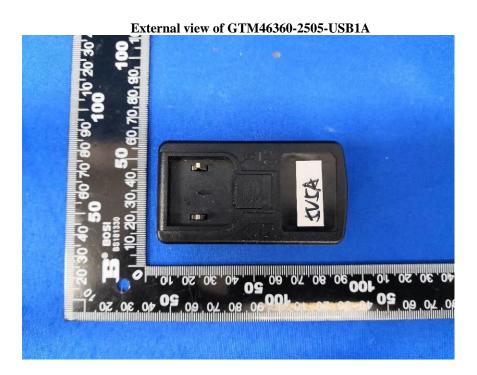




Figure 21.





Figure 22.

PCB of GTM46360-2505-USB1A





Figure 23.



Figure 24.



eurofins

Figure 25.



Figure 26.





Figure 27.

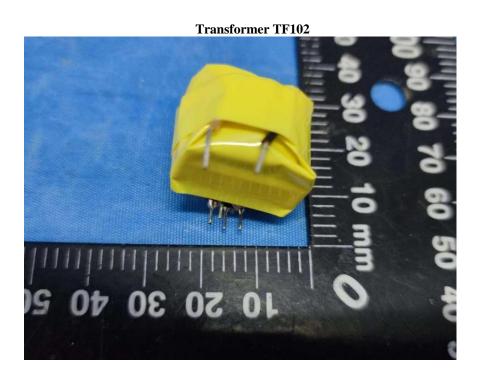
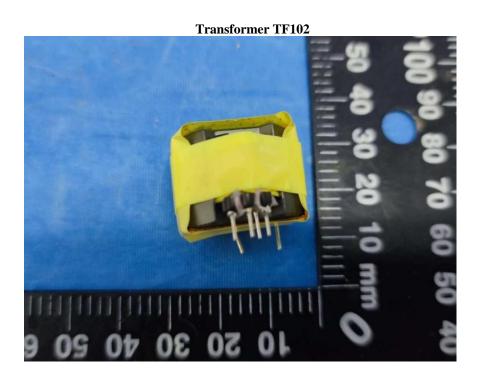


Figure 28.



E&E

eurofins

Figure 29.

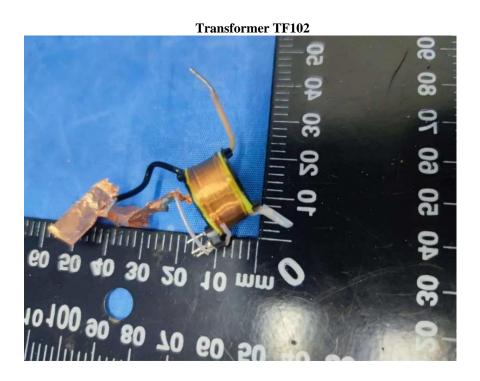


Figure 30.



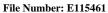




Figure 31.



Figure 32.

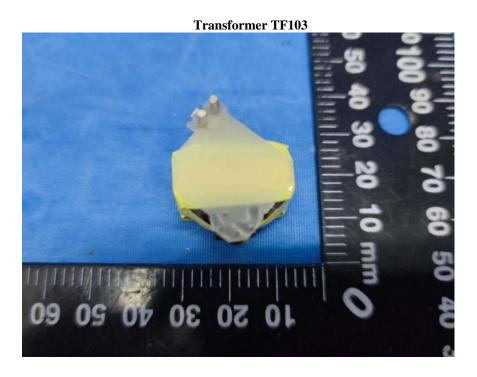


Figure 33.



Figure 34.

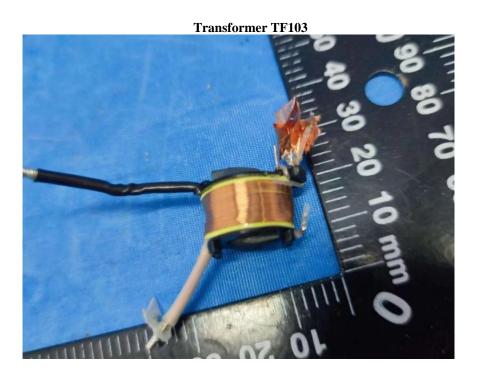
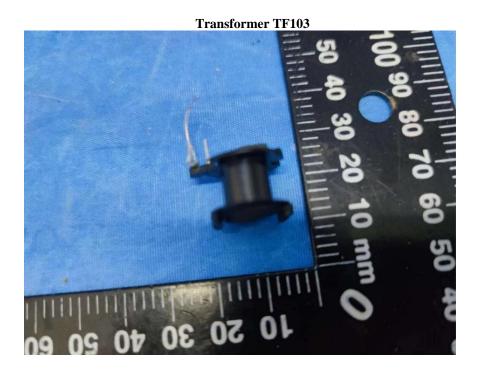


Figure 35.



Figure 36.



E&E

Figure 37.

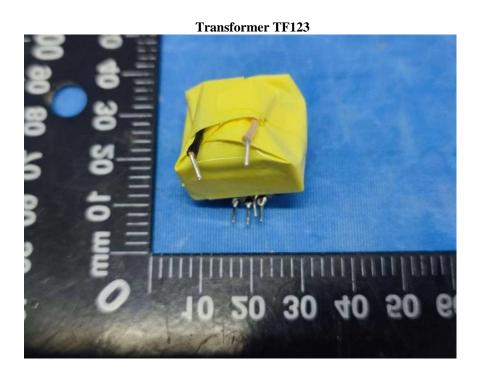


Figure 38.



Figure 39.

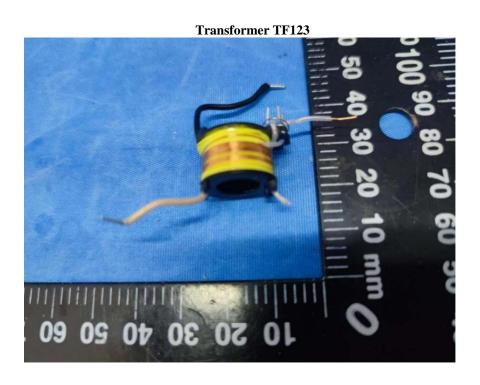
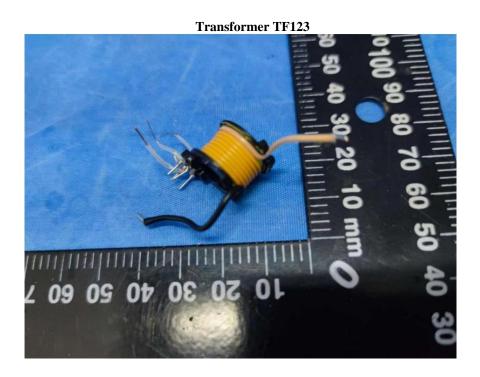


Figure 40.





Illustrations

Illustration 1.



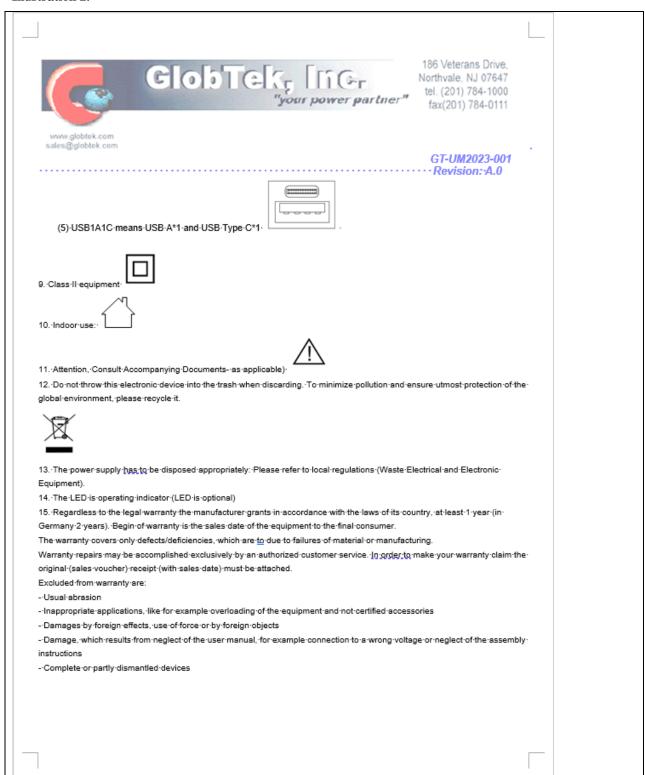
File Number: E115461

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Illustrations (Continued)

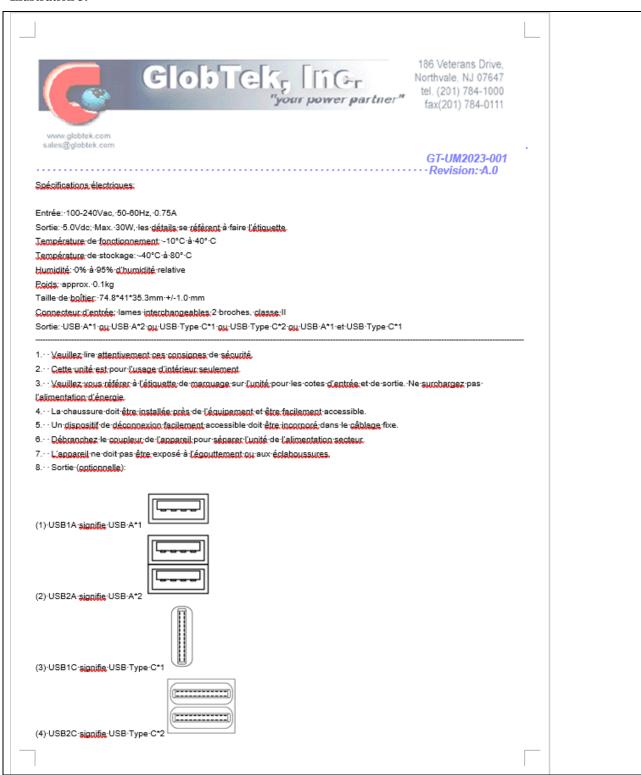
Illustration 2.





Illustrations (Continued)

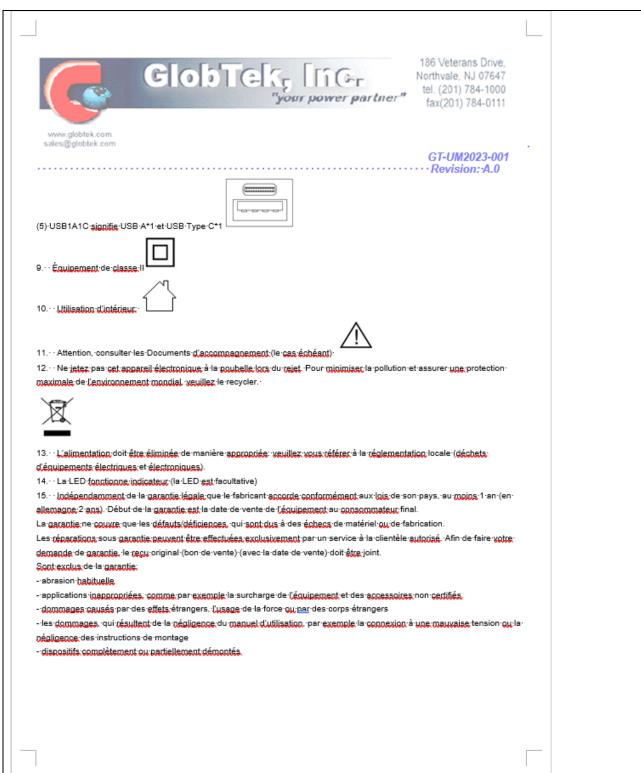
Illustration 3.





Illustrations (Continued)

Illustration 4.



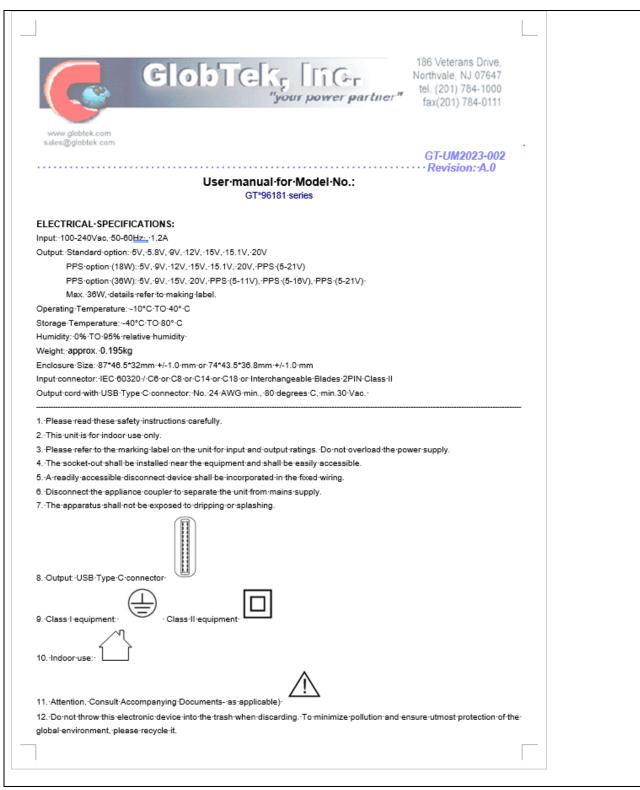


File Number: E115461 MET Report:

MET Report: RecogC130411

Illustrations (Continued)

Illustration 5.

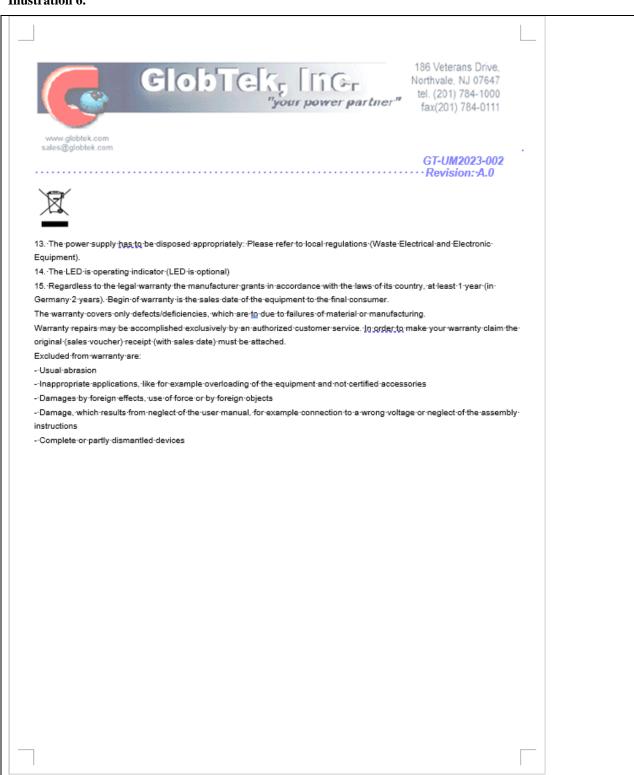






Illustrations (Continued)

Illustration 6.

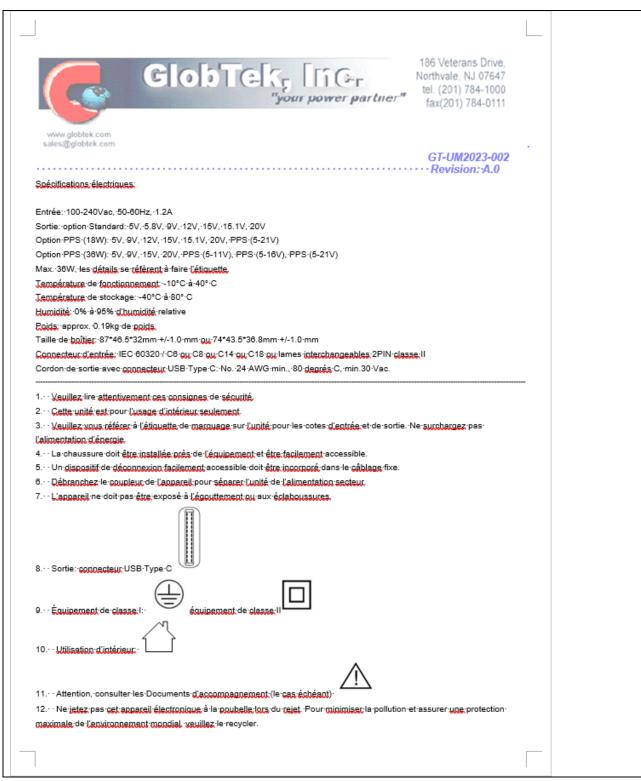






Illustrations (Continued)

Illustration 7.





Illustrations (Continued)

Illustration 8.



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- 13. · · L'alimentation doit être éliminée de manière appropriée: veuillez vous référer à la réglementation locale (déchets d'équipements électriques et électroniques).
- 14. · · La · LED · fonctionne indicateur (la · LED · est · facultative)
- 15. · · Indépendamment de la garantie légale, que le fabricant accorde conformément aux lois de son pays, au moins 1 an (enallemagne, 2-ans). Début de la garantie est la date de vente de l'équipement au consommateur final.

La garantie ne couvre que les défauts/déficiences, qui sont dus à des échecs de matériel ou de fabrication.

Les réparations sous garantie pauvent être effectuées exclusivement par un service à la clientèle autorisé. Afin de faire votre demande de garantie, le recuroriginal (bon de vente) (avec la date de vente) doit être joint.

Sont-exclus-de-la-garantie:

- --abrasion-habituelle.
- applications (pappropriées, comme par exemple la surcharge de l'équipement et des accessoires non certifiés.
- --dommages causés par des effets étrangers, l'usage de la force ou par des corps étrangers
- les dommages, qui résultant de la négligence du manuel d'utilisation, par exemple la connexion à une mauvaise, tension ou la négligence des instructions de montage
- dispositifs complètement ou partiellement démontés.

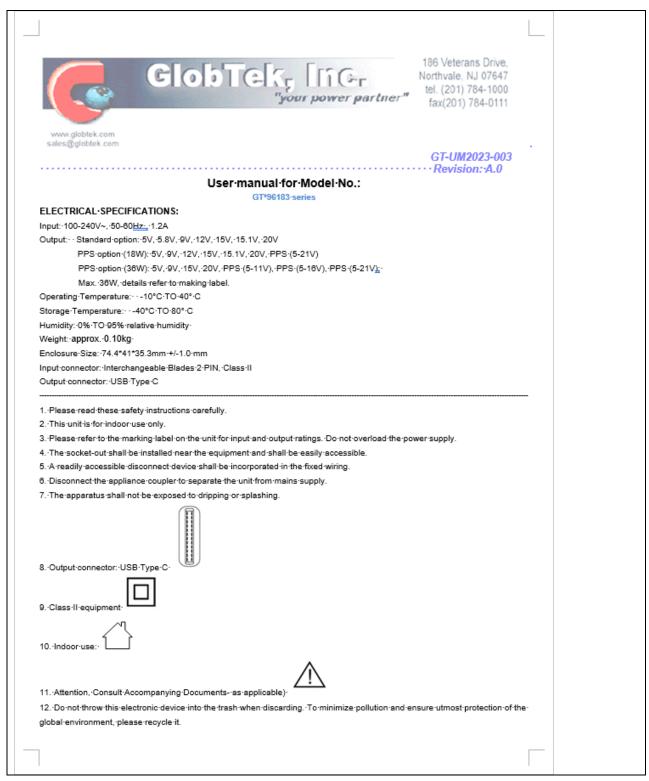


File Number: E115461 MET R

MET Report: RecogC130411

Illustrations (Continued)

Illustration 9.



File Number: E115461 MET Ro



Illustrations (Continued)

Illustration 10.

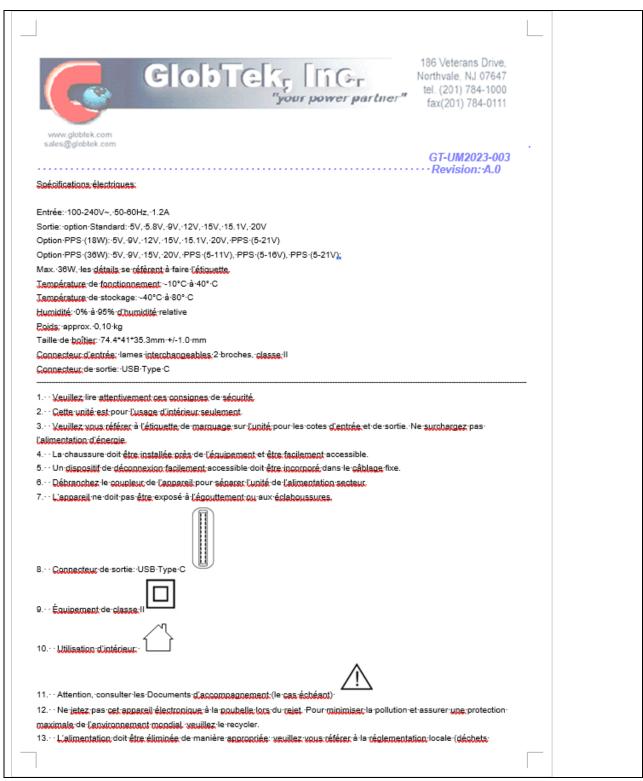






Illustrations (Continued)

Illustration 11.





Illustrations (Continued)

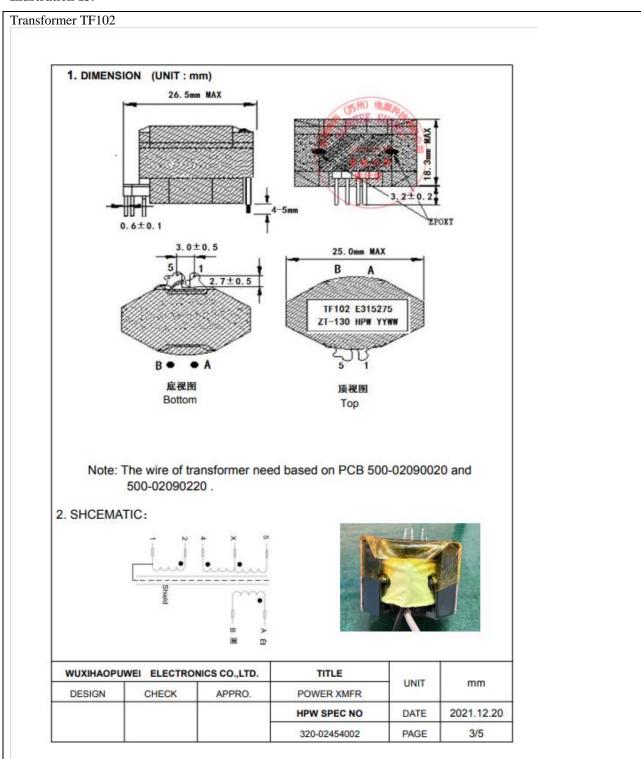
Illustration 12.





Illustrations (Continued)

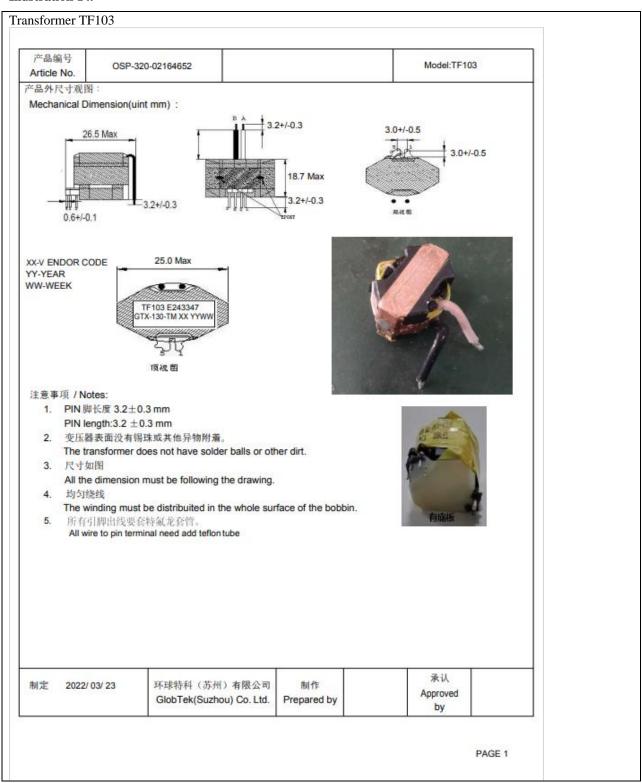
Illustration 13.





Illustrations (Continued)

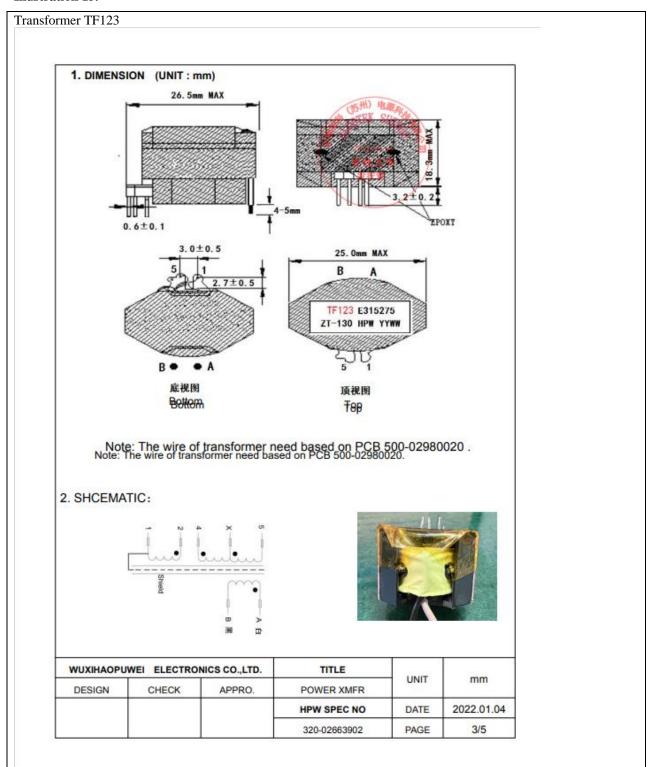
Illustration 14.





Illustrations (Continued)

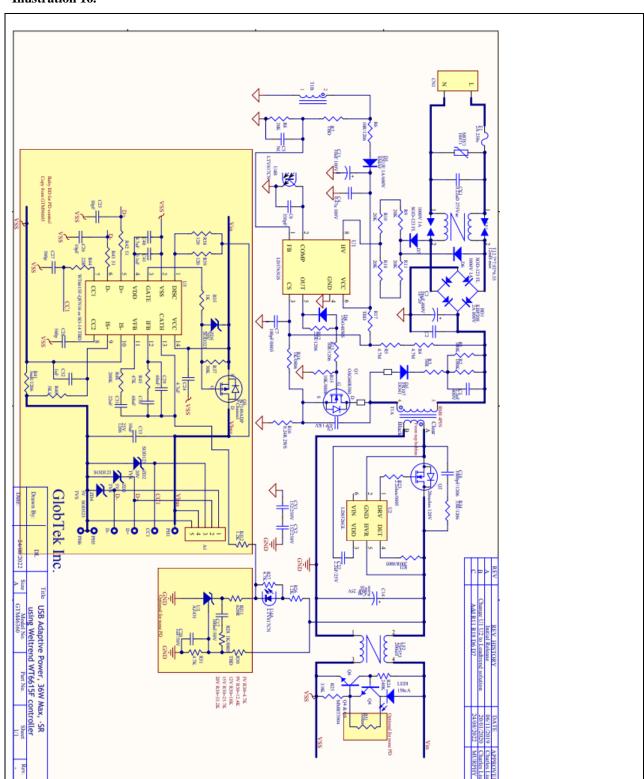
Illustration 15.





Illustrations (Continued)

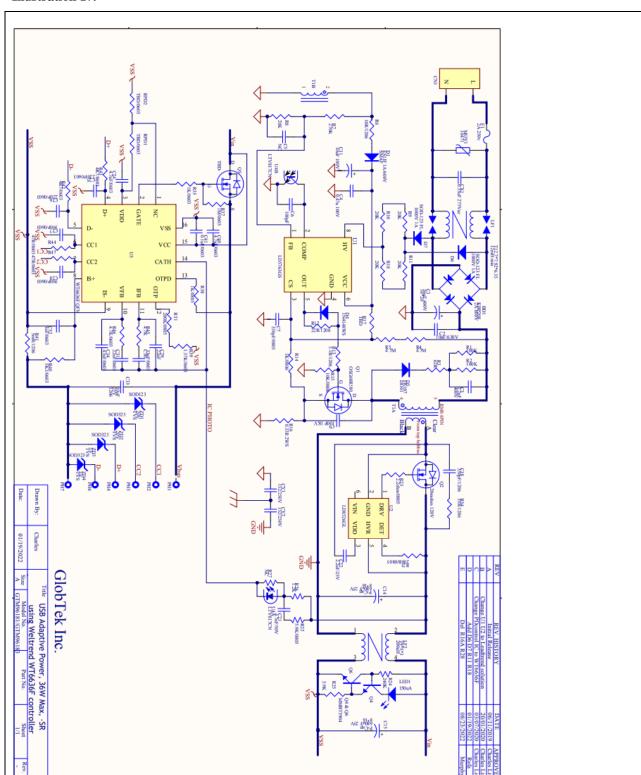
Illustration 16.





Illustrations (Continued)

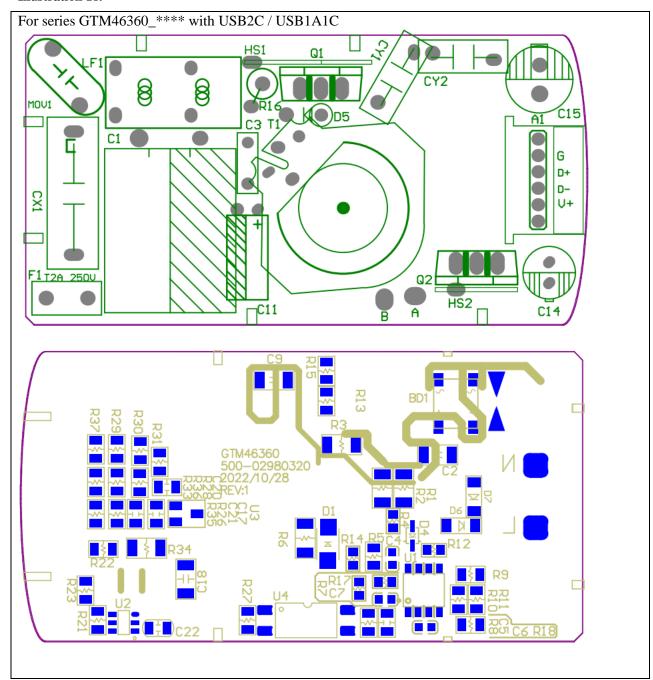
Illustration 17.





Illustrations (Continued)

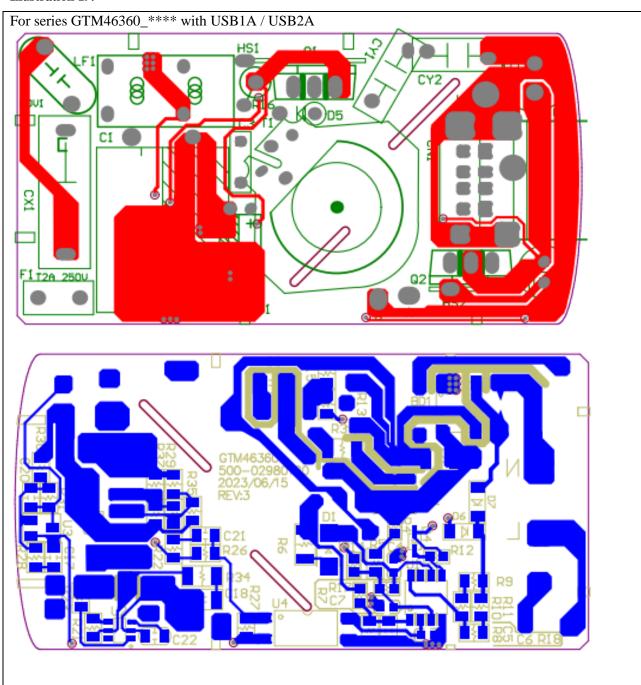
Illustration 18.





Illustrations (Continued)

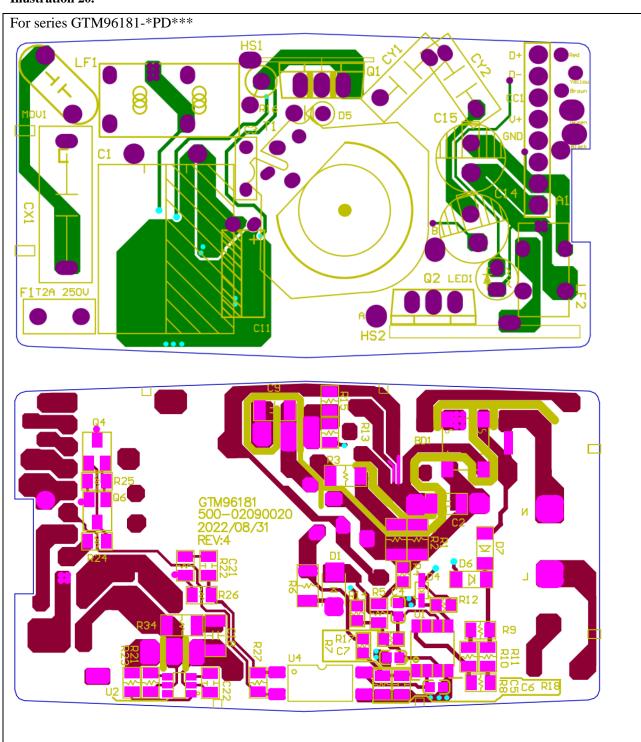
Illustration 19.





Illustrations (Continued)

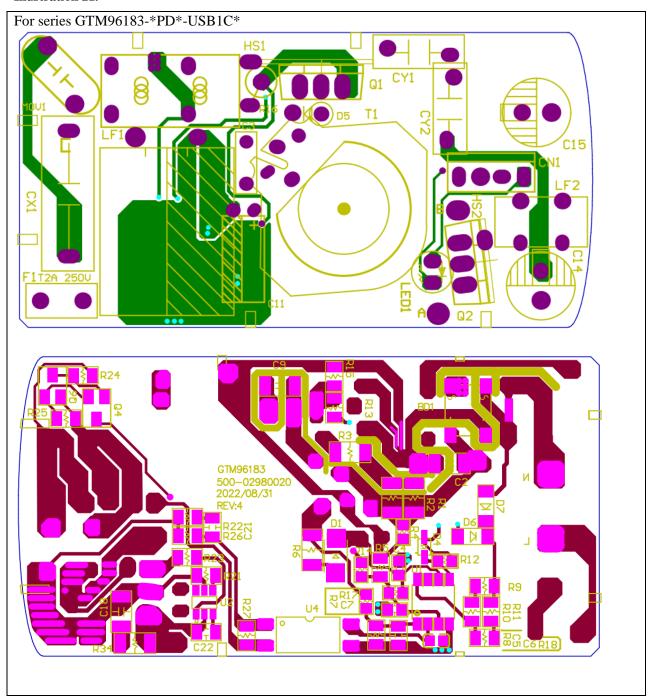
Illustration 20.





Illustrations (Continued)

Illustration 21.





Testing Considerations

Samples of the power supply with model number GTM96183-36PD-USB1C, GTM96181-36PD-T3, GTM96181-36PD-T2, GTM46360-3005-USB2C were subjected to the following test program with satisfactory results. All tests were conducted in accordance with:

ANSI/ AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021, and CAN/CSA-C22.2 No. 60601-1:14+A2:22 (R2022), Medical electrical equipment— Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6 Edition 3.2 2020-07 and CAN/CSA-C22.2 NO. 60601-1-6:11 + A1:15 + A2:21 (R2021) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability;

ANSI/ AAMI HA60601-1-11:2015 [Including AMD1: 2021], CSA C22.2 NO. 60601-1-11:15 (R2020) + A1:21 Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment

Only these tests were considered necessary due to engineering considerations. Detailed test results are on file at MET Laboratories under project number 130411.

TESTS CONDUCTED:

ANSI AAMI ES60601-1, CSA-C22.2 No. 60601-1

Item	Clause	Test
1	5.7	Humidity preconditioning treatment
2	5.9.2	Accessible parts
3	7.1.2	Legibility of markings
4	7.1.3	Durability of markings
5	8.7	Leakage currents and patient auxiliary currents
6	8.8.3	Dielectric strength
7	8.9.4	Measurement of creepage distances and air clearances
8	9.4.2.1	Instability in transport position
9	9.4.2.2	Instability excluding transport position
10	11.1.1	Maximum temperature during normal use
11	13.2	Single fault conditions in accordance with 13.2.2 to 13.2.13
12	15.3	Mechanical strength

ANSI AAMI HA60601-1-11, CSA C22.2 NO. 60601-1-11

Item	Clause	Test
1	4.2.2	Environmental conditions of transport and storage between
		uses
2	4.2.3.1	Continuous operating conditions
3	8.3	Additional requirements for ingress of water or particulate
		matter into me equipment and me systems
4	10.1.2	Requirements for mechanical strength for non-transit-operable
		ME equipment

E&E File Number: E115461 MET Report: RecogC130411

Conclusion

The products covered by this report have been tested, examined, and found to comply with the applicable requirements of ANSI/ AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021, and CAN/CSA-C22.2 No. 60601-1:14 + A2:22 (R2022), Medical electrical equipment—Part 1: General requirements for basic safety and essential performance IEC 60601-1-6 Edition 3.2 2020-07 and CAN/CSA-C22.2 NO. 60601-1-6:11 + A1:15 + A2:21 (R2021) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability; ANSI/ AAMI HA60601-1-11:2015 [Including AMD1: 2021], CSA C22.2 NO. 60601-1-11:15 (R2020) + A1:21 Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment

This certification has been granted under a System 3 program as defined in ISO/IEC Guide 17067.

Prepared By:

Jarle Co

Jack Gan

Project Engineer,

Eurofins Electrical Testing Service(Shanghai) Co.,Ltd.

Reviewed By:

Jackie Zhao Reviewer.

Eurofins Electrical Testing Service(Shanghai) Co.,Ltd.