CSA INTERNATIONAL

Certificate of Compliance

Certificate: 1851838 **Master Contract:** 171413

Project: 1851838 **Date Issued:** 2006/12/01

Issued to: **Globtek Inc.**

186 Veterans Dr.
Northvale, NJ 07647
USA
Attention: na

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US'

C US

Issued by: Abdelkrim Kassou, Jr. Eng.

Authorized by: Helene Vaillancourt,
Operations Manager

Hélène Vaillancourt

PRODUCTS

CLASS 5311 20 - POWER SUPPLIES - Component Type - For Use in Medical Equipment
CLASS 5311 96 - POWER SUPPLIES - Component Acceptance - Certified to US Standards

Direct plug in power supply, rated input: 100-240 Vac, 50-60 Hz, 0.5 A, Models:

- GTM41076-0605; Output: 5 Vdc, 1.2 A
- GTM41076-0606; Output: 6 Vdc, 1.0 A
- GTM41076-0607; Output: 7 Vdc, 0.85 A
- GTM41076-0609; Output: 9 Vdc, 0.66 A
- GTM41076-0612; Output: 12 Vdc, 0.5 A
- GTM41076-0615; Output: 15 Vdc, 0.4 A

The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL, i.e. National Recognized Testing Laboratory, is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

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- GTM41076-0618; Output: 18 Vdc, 0.33 A
- GTM41076-0620; Output: 20 Vdc, 0.3 A
- GTM41076-0624; Output: 24 Vdc, 0.25 A
- GTM41076-0630; Output: 30 Vdc, 0.16 A

Note (*):

- The units were evaluated as components where the suitability of the combination must be determined with the end use product.
- Models differences: Turns ratio of the main transformer and few passive components on the secondary side

APPLICABLE REQUIREMENTS

- CAN/CSA Standard C22.2 No. 601.1-M90 - Medical Electrical Equipment
- UL Standard 60601-1, 1st Edition - Medical Electrical Equipment, Part 1: General Requirements for Safety

CONDITIONS OF ACCEPTABILITY

- 1. This component has been judged on the basis of the required spacings in the Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety, CAN/CSA-C22.2 No. 601.1-M90 and UL 60601-1, 1st Edition, which covers the end-use product for which the component is designed.
- 2. The power supply complies with requirements for reinforced Insulation between primary to secondary.
- 3. The system requires a manual for the medical applications. This product is shipped without a manual, because it was considered as part of an overall product.
- 4. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- 5. The temperature test was performed in a raised ambient of 40 ?C.
- 6. The power supply has been evaluated as Class II equipment, continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- 7. Under normal and single fault conditions, the outputs do not exceed 60 V dc.