CSA INTERNATIONAL

# Certificate of Compliance

**Certificate:** 2178957 **Master Contract:** 163661

**Project:** 2178957 **Date Issued:** September 4, 2009

**Issued to:** **Astec International Ltd.**
**16th and 17th Fl.**
**Lu Plaza, 2 Wing Yip St.**
**Kwun Tong, Kowloon, Hong Kong**

**Attention:** **Mr. Gordhan Hingorani**

***The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US or with adjacent indicator 'US' for US only or without either indicator for Canada only***

C US

**Issued by:** Charles Chow

**Authorized by:** Hans Pan
Area Director, Asia

**PRODUCTS**

CLASS 5311 11 - POWER SUPPLIES - Component Type (CSA 60950-1-07)
CLASS 5311 20 - POWER SUPPLIES - Component Type-For use in Medical Equipment.
CLASS 5311 91 - POWER SUPPLIES - Component Type (UL 60950-1, second Edition) - Certified to U.S. Standards
CLASS 5311 96 - POWER SUPPLIES - Component Acceptance - Certified to US Stds (UL 60601-1, First Edition, NRTL Program) - Certified to U.S. Standards

Component power supply for use with Information Technology/ Electrical Business Equipment and Medical Equipment where the suitability of the combination is to be determined.

Component Type Power Supply, Model iVS8-ABBC-XX(iVS8 series), input rated AC200-240V, 16A, 50/60Hz, 3W+PE; output rated, +5VSB:1.0A, other DC outputs rating vary with the configuration of DC-DC modules, for more details refer to the description of modules in the critical component list of Page 8 and Page 9 in report, total output power not to exceed 4920W for DC outputs excluding +5Vsb output when operated at 50°C ambient temperature, output power decreases at 2.5% per °C from 50°C to 70°C ambient temperatures.

Additional Information: This equipment is considered Class I, with no patient applied part, not suitable for use in the presence of flammable mixtures, continuous operation and detachable cord connected.

1. Type of protection against electric shock: Class I
2. Degree of protection against electric shock: No applied part/Not Classified
3. Degree of protection against ingress of water: IPX0
4. Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous
6. Environmental Conditions: Normal: 10-50°C, 30-75% Rh, 700- 1060 hpa.

**APPLICABLE REQUIREMENTS**

| | | |
|---|---|---|
| CAN/CSA-C22.2 No. 601.1-M90 | - | Medical Electrical Equipment Part I: General Requirements for Safety |
| CAN/CSA-C22.2 No. 601.1S1-94 | - | Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment--Part 1: General Requirements for Safety |
| CAN/CSA-C22.2 No. 601.1B-98 | - | Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment" - Part 1: General Requirements for Safety |
| CAN/CSA C22.2 No 60950-1-07 | - | Information Technology Equipment – Safety Part 1: General Requirements |
| ANSI/UL 60950-1 Second Ed (2007) | - | Information Technology Equipment – Safety Part 1: General Requirements |

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# *Supplement to Certificate of Compliance*

**Certificate:** 2178957 **Master Contract:** 163661

***The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.***

## Product Certification History

| Project | Date | Description |
|---|---|---|
| 2178957 | September 4, 2009 | Original Certification. |

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# Descriptive Report and Test Results

**MASTER CONTRACT:** 163661
**REPORT:** 2178957
**PROJECT:** 2178957

**Edition 1:** September 4, 2009; Project 2178957 - Toronto
Issued by Charles Chow, Reviewed by Sherman Bau (60950) and Sanjay Chaubal (60601)

Contents: Certificate of Compliance – Pages 1 to 2
Supplement to Certificate of Compliance – Page 1
Description and Tests – Pages 1 to 11
Evaluation Document – Checklist 163661-2178956
Bi-National CSA 60950-1-03/UL 60950-1, Second Edition Design Manual, Rev. 1

**PRODUCTS**

CLASS 5311 11 - POWER SUPPLIES - Component Type (CSA 60950-1-07)
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Component power supply for use with Information Technology/ Electrical Business Equipment and Medical Equipment where the suitability of the combination is to be determined.

Component Type Power Supply, Model iVS8-ABBC-XX(iVS8 series), input rated AC200-240V, 16A, 50/60Hz, 3W+PE; output rated, +5VSB:1.0A, other DC outputs rating vary with the configuration of DC-DC modules, for more details refer to the description of modules in the critical component list of Page 8 and Page 9, total output power not to exceed 4920W for DC outputs excluding +5Vsb output when operated at 50°C ambient temperature, output power decreases at 2.5% per °C from 50°C to 70°C ambient temperatures.

Additional Information: This equipment is considered Class I, with no patient applied part, not suitable for use in the presence of flammable mixtures, continuous operation and detachable cord connected.

1. Type of protection against electric shock: Class I
2. Degree of protection against electric shock: No applied part/Not Classified
3. Degree of protection against ingress of water: IPX0
4. Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous
6. Environmental Conditions: Normal: 10-50°C, 30-75% Rh, 700-1060 hpa.



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**APPLICABLE REQUIREMENTS**

| | | |
|---|---|---|
| CAN/CSA-C22.2 No. 601.1-M90 | - | Medical Electrical Equipment Part I: General Requirements for Safety |
| CAN/CSA-C22.2 No. 601.1S1-94 | - | Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment--Part 1: General Requirements for Safety |
| CAN/CSA-C22.2 No. 601.1B-98 | - | Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment" - Part 1: General Requirements for Safety |
| CAN/CSA C22.2 No 60950-1-07 | - | Information Technology Equipment – Safety Part 1: General Requirements |
| ANSI/UL 60950-1 Second Ed (2007) | - | Information Technology Equipment – Safety Part 1: General Requirements |

Subject to the following qualifications:

(1) The equipment has not been investigated for the protection against hazards of explosions in medically used rooms.

(2) The equipment has been evaluated to the above standards excluding requirements for Electromagnetic Compatibility (Cl 56), Biocompatibility (Cl 48), and Programmable Electronic Systems (Cl 52.1).

(3) Component Power supplies for use in other equipment where the acceptability of the combination is to be determined.

(4) An appropriate enclosure is to be provided in the end-use application.

BI-NAT CSA 60950-1-07/UL 60950-1, Second Edition DESIGN MANUAL, Revision 1.0 (ISSUED WITH 1467153)IS AN INTEGRAL PART OF THIS REPORT

Unless otherwise specified, all clauses are referring to CSA 601.1

## MARKINGS

MARKING METHOD: The markings below are made via silk screening, die stamping, moulding or on CSA certified or UL recognized adhesive nameplate material compatible with the surface used, or equivalent permanent means that can pass the label rub test under Cl 6.1

(a) The CSA applicable mark / / with optional reference to Standard CAN/CSA C22.2 No. 601.1 (AM1+AM2), UL 60601-1, or IEC 60601-1

(b) Manufacturer's identification: Name and/or CSA file number "LR 53982" or Master Contract "163661" on the same label as the CSA Mark. The name and/or trademark should appear elsewhere on the equipment if only the file number or Master Contract is used on this label.

(c) Catalogue/Model/Type designation.

(d) Electrical rating: The complete electrical ratings (in volts, hertz and amperes) with the IEC 60417-5032 ~ "Alternating current symbol" or with IEC 60417-503 ⎓ "DC Current symbol" adjacent to the marked voltage/s.

(e) Date of manufacture: Month and year of manufacture or date code. If a serial number is used instead of date of manufacture, a record of serial numbers shall be kept traceable to date of manufacture. (Not related to date of sale).

(f) Type of protection against electrical shock: Class I for protectively grounded equipment. (May be marked on the product or recorded in accompanying documents)

(g) Degree of Protection against Harmful Ingress of Water: Ordinary equipment, IPX0. (Marking is not required if it is IPX0)

(h) Degree of Safety in the Presence of Flammable Anaesthetic Mixture with Air or Oxygen or Nitrous Oxide: Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. (May be marked on the product or recorded in accompanying documents)

(i) Mode of Operation: Continuous.

(j) Fuse (Three poles fusing): (CSA 60950-1, Clause 2.7.6, NAA)

Notes:

Jurisdictions in Canada may require these markings to be also in French. It is the responsibility of the Customer to provide bilingual marking, where applicable, in accordance with the requirements of the Provincial Regulatory Authorities. It is the responsibility of the Customer to determine this requirement and have bilingual wording added to the "Markings".

All words comprising the text of the marking shall be not less than 1.6mm (1/16 inch) high, based upon upper case; all signal words (CAUTION, WARNING and DANGER), shall be 2.8mm (7/76 inch).

If size of equipment does not allow affixation of all specified markings, the remaining marking shall be recorded in full in the accompany document.

On the equipment interior:

- The IEC 60417-5019 protective earth symbol ⏚ adjacent to the earthing terminal.

- Interchangeable fuses accessible only with the aid of a tool shall be identified either by type and rating next to the fuse on the pcb or near the fuseholder or by at least a reference traceable in the Technical Manual.

Accompanying documents are the Instruction for Use and Technical Description:

An instruction for use is provided that specifies signal inputs and outputs, proper operating procedures for the equipment, recommended accessories, replacement parts, proper cleaning, operator maintenance procedures, maintenance information, and technical characteristics and specifications.

The Technical description includes a statement that the supplier will make available on request, circuit diagrams, component part lists, etc.

All accompany documents include the following:

- Glossary of symbols used on the product and in accompanying documents.
- All markings, symbols and warning statement appearing on the equipment.
- The environmental conditions for storage and transport appear in the instruction for use and on the package label.
- Following classifications:
  - Degree of protection against shock;
  - Shock protection;
  - Protection against harmful ingress of water;
  - Degree of safety in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide;
  - Mode of operation.

## ALTERATIONS

Markings as above shall appear on each unit.

## SPECIAL INSTRUCTIONS FOR FIELD SERVICES

1. Component Substitution
   a) Critical components (those identified by mfr name, cat no) are not eligible for substitution without evaluation and report updating.
   b) Component descriptions marked with the identifier "(CT)" are subject to annual pickup and Conformity Testing.
   c) Component descriptions marked with the identifier "(INT)" are the only components that are eligible for substitution at the factory.
   d) Substitution of a CSA Certified component with a component "Certified" or "Listed" by another organization may result in annual sample pickup and Conformity Testing.
   e) Substitution of a "Certified" or "Listed" component with a component that is "Recognized" or "Accepted" is not permitted without evaluation and report updating.

## FACTORY TESTS

DIELECTRIC STRENGTH

Equipment: The equipment at the conclusion of manufacture, before shipment, shall withstand for one minute, without breakdown, the application of 3038/6742Vdc between live parts and exposed metal parts protectively earth / non-protectively earth.

Transformers connected to the AC Supply: Each transformer before assembly into the equipment shall be subjected to the following dielectric strength tests for a period of one minute, without breakdown. The factory test may be conducted at existing room temperature.

An AC potential applied between each winding and the core and metal enclosure for transformer used in case (73-670-0001I) and DC-DC modules, with all other windings grounded to the core and metal enclosure. The potential shall be:

(a) For Primary Windings to core - 4767V ac.
(b) For Primary Windings to Secondary Windings - 4767V ac.

Note: As an alternative, a potential 20 percent higher may be applied for one sec. Coupling components within the product may require tests to be conducted using DC voltages. Where DC voltages are used, the test values are increased by 1.414 times the AC voltages.

LEAKAGE CURRENT:

Measurement of the earth leakage according to CAN/CSA C22.2 No 601.1, Clause 19 and Fig 16 using the measuring circuit of Fig 10, at ambient temperature but without a moisture preconditioning treatment.

In cases where the number of settings of parameters of the equipment of switches of the measuring supply circuit or of the application of a metal foil or the application of the measuring device, to be performed during the test would be unacceptable and the results of certain tests would indicate the highest value(s), then the routine tests may be restricted to the setting(s) provoking these values.

GROUND CONTINUITY:

The equipment shall be tested for ground continuity by means of an ohmmeter or battery and buzzer combination as a minimum.

An alternative test method follows: A current not less than 10A and not exceeding 25A from a current source with a frequency of 50 or 60Hz with a no-load voltage not exceeding 6V is passed through the protective earth contact in the mains terminal block and accessible metal parts which are intended to be earthed. The voltage drop between the earthing terminal of the machine and accessible metal parts is measured and the impedance calculated from the current and voltage drop. The impedance between the protective earth pins of the power supply cord/protective earth terminal and any accessible metal part which is protectively earth in no case shall the resistance exceed 0.2/0.1 ohm. The machine if provided with a power supply cord is tested with that cord, and if provided with a detachable cord set tested with that cord set, or if test without, the cord set is tested separately.

Warning: The factory test(s) specified may present a hazard of injury to personnel and/or property and should only be performed by persons knowledgeable of such hazards and under conditions designed to minimize the possibility of injury.

## DESCRIPTION

Notes:
1. The term "(INT)", following the component name, denotes a certified component that can be replaced by one from another certified source (approved by OSHA/SCC accredited body for the same application) provided that it has an equivalent rating, configuration (size, orientation, mounting) and that applicable minimum creepage and clearance distances are maintained from live parts to bonded metal parts and secondary parts.
2. The term "(CT)", following the component name, denotes a component that is subject to periodic re-testing unless evidence of re-testing equivalent to the CSA program is available.

## INTRODUCTION

A representative sample of the subject product was examined and is described in the body of this report. Unless specifically stated otherwise, the following general definitions, terminology and construction details apply:

Asterisk: In "Certified*" the asterisk denotes that the CSA Monogram appears on the component. An asterisk behind any other test house's name denotes that their monogram appears on the component.

ELV: All references to "ELV" denote Extra Low Voltage (less than 42.4V peak) secondary circuits.

UL: "UL R/C" or "UR" means Underwriters' Laboratories Inc's recognized components and "UL Listed" or "UL" means Underwriters' Laboratories Inc's Listed components.

TUV: TUV Certified and suitable for the application.

VDE: VDE Certified and suitable for the application.

Metal: All references to "metal" denote painted or plated steel (min No. 20 MSG) or aluminium (min No. 16 AWG).

Dimensions: (dim) All dimensions specified are approximations only.

Internal Wiring: All primary and grounding circuit conductors are Certified and UL Recognized, rated min 80 °C, 300 V ac. All wiring is suitably routed and secured away from sharp edges and moving parts to prevent chafing of the insulation. Alternatively, additional insulation is provided where the wiring passes over sharp edges and through holes. All mains circuit wiring shall be doubly secured at all connection points.

ELV Wiring: All non-certified conductors and connectors in ELV sec circuits have insulation materials with a flammability rating of 94V-2 or better or are made of PVC, TFE, PTFE, FEP or Neoprene and are routed and secured away from contacting all primary circuitry.

Sleeving: All thermoplastic and other insulating tubing used in primary circuits are certified and UL Recognized, rated min 105°C, 300V ac.
Crimp Connectors: All crimp-type connectors used in primary and grounding circuits are certified and UL Recognized and appropriately sized for the gauge of conductors used, vinyl insulated (optional for grounding), rated min 90°C , 250V ac.

Connectors: All connectors used in primary circuits are certified and UL Recognized, appropriately sized for the number and gauge of conductors used, rated min 250V ac.

Printed Wiring Boards (PWB): All PWB's are made of paper phenolic, paper epoxy or glass epoxy, min 1.6mm thick, flammability rated 94V-2 or better.

Bonding: All accessible metal parts liable to become energized are acceptably connected together, and to the grounding means, by straps and/or conductors, bolts, screws and star washers (to ensure surface coating penetration).

Spacings: All spacing between terminals, between pwb conductive traces, and between other bare live parts and ground, conform to Table XVI of CSA Standard C22.2 No 601.1, Clause 57.10.

Equivalent: The notation "or equiv" denotes that: an alternative component having equivalent safety approvals and similar mechanical and electrical characteristics may be used; or the marked wording having equivalent information and intent may be used.

**DESCRIPTION**

Models iVS8-ABBC -xx

General: Component Power Supplies for use in other equipment where the acceptability of the combination is to be determined.

(a) Class of Equipment: Class I (grounded)

(b) Connection to Supply: Terminal

(c) Type of Power System: TN-S

(d) Mobility: For building- in

(e) Weight of Equipment: < 18 kg

(f) Pollution Degree 2: Not sealed, not subject to dust, dirt, condensation.

(g) Maximum Rated Ambient Temperature: Rated for maximum ambient temperature of 50°C for normal fan airflow direction which blows air towards the components and 40°C for reversible fan airflow direction with the same full power of 4920W.

General: Component Power supplies for use in other equipment where the acceptability of the combination is to be determined.

| Object/part No | Manufacturer/ trademark | Type/model | Technical data | Standard | Mark(s) of conformity[1]) |
|---|---|---|---|---|---|
| AC-DC Converter (Front-End Module) (INT) | Astec or Emerson | 73-670-0001I | Input: AC200-240V, 3 phase, 12A, 50/60Hz, Outputs:380Vdc, 5300W max. +5VSB,1.0A, M1Vcc to M14Vcc,0.1A | CSA/UL/IEC 60950-1 | CSA,UL, TUV |
| DC-DC Modules (Single Output) 1500W (INT) | Astec or Emerson | 73-558-0012i 73-558-0015i 73-558-0024i 73-558-0048i | Input rated: 380Vdc, 4.5 A Output rated: +6 to +60Vdc (maximum 1500W) | CSA/UL/IEC 60950-1 | CSA, UL, TUV |
| DC-DC Modules (Single Output) 750W (INT) | Astec or Emerson | 73-553-0005i 73-553-0012i 73-553-0015i 73-553-0024i 73-553-0048i | Input rated: 380Vdc, 2.7 A Output rated: +2.0 to +60Vdc (maximum 750W) | CSA/UL/IEC 60950-1 | CSA, UL, TUV |
| DC-DC Modules (Single Output) 360W (INT) | Astec or Emerson | 73-552-0005i 73-552-0012i 73-552-0015i 73-552-0024i 73-552-0048i | Input rated: 380Vdc, 1.6 A Output rated: +2 to +60 Vdc (maximum 360W) | CSA/UL/IEC 60950-1 | CSA, UL, TUV |
| DC-DC Modules (Single Output) 210W (INT) | Astec or Emerson | 73-551-0005i 73-551-0012i 73-551-0015i 73-551-0024i 73-551-0048i | Input rated: 380Vdc, 1.0 A Output rated: +2 to +60 Vdc (maximum 210W) | CSA/UL/IEC 60950-1 | CSA, UL, TUV |
| DC-DC Modules (Dual Output) 144W (INT) | Astec or Emerson | 73-554-0220i 73-554-0320i 73-554-0330i 73-554-0350i 73-554-0520i 73-554-0550i | Input rated: 380Vdc, 0.6 A Output rated: +2 to +28 Vdc, (maximum 144W) | CSA/UL/IEC 60950-1 | CSA, UL, TUV |
| DC-DC Modules (Triple Output) 36W (INT) | Astec or Emerson | 73-550-0332i 73-550-0333i 73-550-0335i 73-550-0352i | Input rated: 380Vdc, 0.4 A Output rated: +2 to +28 Vdc, | CSA/UL/IEC 60950-1 | CSA, UL, TUV |

| | | | | | |
|---|---|---|---|---|---|
| | | | (maximum 36W) | | |
| Fanof AC-DC Converter (Front-End Module) | SANYO DENKI Co. Ltd | 9G0912P2 series | 12Vdc, 0.88A (Dimensions: 90mm x 90mm) | UL 507 | UR (C-US) (File No. E46810) |
| | SUNONWEALTH ELECTRIC MECHINERY INDUSTRY CO. LTD | PMD1209PLB1 | 12Vdc, 7.8W (Dimensions: 90mm x 90mm) | | UR (C-US) (File No. E77551) |

For Detailed Engineering Consideration: Refer to the attached CSA Evaluation Document (Ref. No. CB 163661 –2178956)

For CSA Field Inspection: Refer to the following sections of the attached CSA Evaluation Document for model iVS8-ABBC -xx (Ref. No. CB 163661 – 2178956)

- Photos ..... Att 2
- Model Configuration ..... Att 3
- Installation and Operating Instructions……...Att 3
- Ventilation Airflow ..... Att 3
- Enclosure Mechanical Drawings ..... Att 5
- Certifications/Approvals..... Att 4

**TESTS**

Refer to attached CSA Evaluation Document, CB 163661 –2178956

CSA 60601-1 testing and evaluation is based on acceptance of CSA IEC 60950-1 CB certificate and report - 163661-2178956. The following additional tests were performed on a sample of component power supply, Model iVS8-ABBC-xx to verify compliance to CSA 601.1 and UL 60601-1; details are kept in the 601.1 checklist at the Toronto Office.

CSA 601.1 and UL 60601-1 Tests:

1. Dielectric Strength, Clause 20. ----Mar 09, 2009
2. Humidity, Clause 4.10. ----Mar 07-Mar 09, 2009
3. Leakage Current, Clause 19:
   a. Earth Leakage, Clause 19.4 f), Fig 16 to 17 as applicable.----Apr 13, 2009
   b. Enclosure Leakage, Clause 19.4 g), Fig 18 to 19 as applicable.----Apr 13, 2009
4. Creepage and Clearance, Clause 57.10. ----Mar 09, 2009
5. Marking on Equipment, Clause 6.----Apr 13, 2009