CSA INTERNATIONAL

Certificate of Compliance

Certificate: **Master Contract:** 163059

Project: 2470093 **Date Issued:** January 2, 2012

Issued to: **Communications & Power Industries Canada Inc.**
45 River Dr
Georgetown, ON L7G 2J4
Canada
Attention: Tony Nguyen

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

Daniel Peressotti

Issued by: Daniel Peressotti

PRODUCTS

CLASS 8750 01 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS 8750 81 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS - Certified to US Standards

Mobile X-ray Generator, Model VZW2559RH11-YY (where YY = 00 to 99 representing other hardware and software options not related to electrical safety), rated input: 240Vdc, 1A (70A momentary), rated output: 40 to 150kV, 32kW max.

1. Type of protection against electric shock: Class I /Battery operated
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 anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
5. Mode of operation: Continuous with Intermittent loading

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6. Environmental Conditions: Normal: 10-40°C, 20-80% rH (non-condensing), 700-1100hP

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA C22.2 601.1-M90	Medical Electrical Equipment part 1: General requirements for Safety adopted IEC 601-1 2ed (90)
CAN/CSA C22.2 601.1S1-94	Supplement No 1-94 to CAN/CSA C22.2 601.1-M90
CAN/CSA C22.2 601.1B-98	Amendment 2 to CAN/CSA C22.2 601.1-M90
CAN/CSA-C22.2 No. 60601-2-7-01 (R2005)	Medical Electrical Equipment - Part 2-7: Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-Ray Generators (Adopted IEC 60601-2-7:1998, second edition, 1998-02)

UL Standards:

UL 60601-1 (1st edition)	Medical Electrical Equipment part 1: General requirements for Safety

Subject to the following qualifications:

(1) The subject equipment has been evaluated as a Class I device, a connection to protective earth is required and shall be provided as part of the end use system.

(2) The generator has been evaluated as a component only; it shall require evaluation for suitability in the end use application.

(3) The user replaceable mains (line) fuse must be an approved type acceptable to the authorities where the equipment is sold.

(4) Evaluated to IEC/CSA 601□1 Amendment 2 excluding requirements for Electromagnetic compatibility (Clause 36), Biocompatibility (Clause 48), Programmable Electronic Systems (IEC 60601□1□4 referenced in sub□clause 52.1), 60601-1-6 and 60601-1-8.

(5) SAFETY **HAZARDS** resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

(6) Interconnection of this medical device with other medical devices, medical used systems or non medical devices shall be evaluated to the requirements of CSA/IEC 60601-1-1 in the end use application.

(7) The connectors on the power cord used to connect the generator to the DC supply shall be evaluated for protection against contact with live parts in the end use application.

(8) The end use system shall provide means to isolate the generator circuits electrically from the supply mains on all poles simultaneously.

(9) The end use system shall provide an enclosure which meets the relevant mechanical strength requirements of clause 21 of 60601-1.

(10) Earth leakages shall be performed as part of the end system evaluation.

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Supplement to Certificate of Compliance

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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
2470093	January 2, 2012	Original Certification