



Certificate of Compliance

Certificate: 70028887 **Master Contract:** 163059 (097383_C_000)

Project: 70086421 **Date Issued:** 2016-07-06

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

The products listed below are eligible to bear the CSA Mark shown



Issued by: *Timothy Stafrace*
Timothy Stafrace, C.E.T.

PRODUCTS

CLASS - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS

CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS-Certified to US Standards

Diagnostic X-Ray Generators, CMP 200 Series and CMP 200DR Series, permanently connected, models:

Part A:

80 kW Series:

VZW2556RD2-YY: rated 400/480V, 3P, 50/60Hz, Rad.

VZW2556RD3-YY: rated 480/400V, 3P, 50/60Hz, Rad.

65 kW Series:

VZW2556RC2-YY: rated 400V, 3P, 50/60Hz, Rad.

VZW2556RC3-YY: rated 480V, 3P, 50/60Hz, Rad.

50 kW Series:

VZW2556RB2-YY: rated 400V, 3P, 50/60Hz, Rad.

VZW2556RB3-YY: rated 480V, 3P, 50/60Hz, Rad.

VZW2556RB4-YY: rated 208/230V, 3P, 50/60Hz, Rad.



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40 kW Series:

VZW2556RE2-YY: rated 400V, 3P, 50/60Hz, Rad.

VZW2556RE3-YY: rated 480V, 3P, 50/60Hz, Rad.

VZW2556RE4-YY: rated 208/230V, 3P, 50/60Hz, Rad.

VZW2556RE5-YY: rated 208/230V, 1P, 50/60Hz, Rad.

32 kW Series:

VZW2556RH2-YY: rated 400V, 3P, 50/60Hz, Rad.

VZW2556RH3-YY: rated 480V, 3P, 50/60Hz, Rad.

VZW2556RH4-YY: rated 208/230V, 3P, 50/60Hz, Rad.

VZW2556RH5-YY: rated 208/230V, 1P, 50/60Hz, Rad.

Note: In the Generator model number the eighth character will be designated "R". "R" is used to indicate Radiographic.

The ninth and tenth characters respectively indicate the Generator power level and the compatible input voltage connected directly to the unit.

The suffix YY is between "00" and "99" and "AA to ZZ", which represents other hardware and software options (not affecting safety) provided in the generator configuration and available to most models.

Part B:

CMP 200 Series and CMP 200DR Series, Energy Assist Generator:

50 kW Series:

VZW2562ARB511-YY: rated 208/230V, 1P, 50/60Hz, Rad.

Note: In the Generator model number the 8th and 9th character will be "A" and "R". "A" is indicated for "Energy Assist Generator" and "R" for Radiographic.

The 10th and 11th characters respectively indicate the Generator power level (B= 50kW) and the compatible input voltage (5= 208/230V) connected directly to the unit.

The 12th and 13th characters respectively indicate 1 tube and 1 filament.

The suffix YY is between "00" and "99" and "AA to ZZ", which represents other hardware and software options (not affecting safety) provided in the generator configuration and available to most models.



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Part C:

CMP 200PF Generators:

Model no.: VZW2556PL3-YY, rated 12.5kW, 480/400V, 3P, 50/60Hz, 22/25A momentary, 5A nominal.

Model no.: VZW2556PM2-YY, rated 48kW, 400/480, 3P, 50/60Hz, 92/75A momentary, 5A nominal.

Note: “P” indicates Radiographic and Pulsed Fluoro.
“L” indicates 12.5kW and M 48kW power level.

The suffix YY is between "00" and "99" and “AA to ZZ”, which represents other hardware and software options (not affecting safety) provided in the generator configurations.

Part D:

CMP 200 Series and CMP 200DR Series, Energy Assist Generator:

32 kW Series:

VZW2562ARH511-YY: rated 208/230V, 1P, 50/60Hz, Rad.

40 kW Series:

VZW2562ARE511-YY: rated 208/230V, 1P, 50/60Hz, Rad.

Note: In the Generator model number the 8th and 9th character will be “A” and “R”. “A” is indicated for “Energy Assist Generator” and “R” for Radiographic.

The 10th and 11th characters respectively indicate the Generator power level (H= 32kW and E= 40kW) and the compatible input voltage (5= 208/230V) connected directly to the unit.

The 12th and 13th characters respectively indicate 1 tube and 1 filament.

The suffix YY is between "00" and "99" and “AA to ZZ”, which represents other hardware and software options (not affecting safety) provided in the generator configuration and available to most models.

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. 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.
6. Environmental Conditions: Temperature: 10-40°C, rH: 20-80% (non-condensing), Atmospheric Pressure: 700-1100hPa.



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APPLICABLE REQUIREMENTS

CSA Standards:

- CAN/CSA-C22.2 No. 60601-1-08 Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance
- CAN/CSA-C22.2 NO. 60601-1:08 TC 2:2011 (Corrigendum 2) Technical Corrigendum 2:2011 to CAN/CSA-C22.2 No. 60601-1-08, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12)
- CAN/CSA-C22.2 NO. 60601-2-54:11 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
(Adopted IEC 60601-2-54:2009, first edition, 2009-06)

ANSI/AAMI Standards:

- ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD) Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
- ANSI/AAMES60601-1:2005/C1:2009 (Coorigendum 1) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Corrigendum 1

IEC Standards:

- IEC 60601-2-54:2009 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy



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Subject to the following qualifications:

- 1) CMP 200/DR X-ray generators are intended for use in stationary radiographic applications, for medical diagnostic purposes. The X-ray generator consists of a main power cabinet that houses the control electronics and the High Voltage Module (HVM) and a Control Console. The generator may be supplied with a Rad-only membrane console, a touchscreen console, or a mini-console control unit. The mini-console control unit provides on/off and prep/X-ray controls and indicators only and is used with digital imaging systems that have integrated generator controls.
- 2) The user replaceable mains (line) fuse must be an approved type acceptable to the authorities where the equipment is sold.
- 3) Evaluated to CAN/CSA-C22.2 No. 60601-1-08 and ANSI/AAMI ES60601-1:2005 excluding requirements for Electromagnetic compatibility (Clause 17), Biocompatibility (Clause 11.7), Programmable Electronic Systems (Clause 14), Usability (Clauses 7.1.1 & 12.2) & Alarms (Clause 12.3 & CSA 60601-1-8).
- 4) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
- 5) Interconnection of this medical device with other medical devices, medical used systems or non-medical devices shall be evaluated to the requirements of Clause 16 in the end use application.
A means to disconnect from mains on all poles shall be provided in the end use system.



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
70086421	2016-07-06	Update to CSA Report to cover other hardware and software options provided in the generator configuration ("AA" to "ZZ"), not affecting safety.
70028887	Apr 2, 2015	Alternate fuses (F8, F9, rated 4A) to be used for HV Aux board 400/480V (739442-XX) and removal of EMI filter (FN-258P-100-35) for Model no. VZW2556PM2-01 (listed in Part C).
2716360	Apr 7, 2014	Alternate constructions to models listed in Part A & C of the Report; new fuse value for DSS board (728877-XX) and alternate CAN DSS (903132-XX).
2682814	Dec 4, 2013	Update to the Report to cover new model VZW2556PM2-YY and critical component list revision.
2644865	Jul 16, 2013	Update to Report 2556968 to cover new models VZW2556PL3-YY, VZW2556PB2-YY, VZW2562ARH511-YY & VZW2562ARE511-YY.
2600520	Feb 6, 2013	Update 2556968 to cover addition of Energy Assist Module.
2556968	Oct 3, 2012	Original Certification to 60601-1 3rd Ed.