Certificate of Compliance

Certificate: 2701600 **Master Contract:** 163059 (097383_C_000)

Project: 70084496 **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

Part A:

Diagnostic X-Ray Generator (RAD & FLUORO); Indico IQ; Model VZW2558FJ8YY rated 100kW, 400-480V, 3P, 50/60Hz, 210-165A momentary, 0.5A nominal and Model VZW2558FD8YY rated 80kW, 3P, 50/60Hz, 168-140A momentary, 0.5A nominal; permanently connected with no patient applied parts.

Part B:
Model VZW2558FC8YY rated 65kW, 400-480V, 3P, 50/60Hz, 135-115A momentary, 0.5A nominal; permanently connected with no patient applied parts.

Part C:
Model VZW2558FB8YY rated 50kW, 400-480V, 3P, 50/60Hz, 100-80A momentary, 0.5A nominal; permanently connected with no patient applied parts.

Part D:

VMS 150 Stand Alone Generator

Model VZW2949FH2-YY rated 32kW, 400-480V, 3P, 50/60Hz, 65-55 momentary, 5A nominal; permanently connected with no patient applied parts. This generator does not include an Operator Control Console.

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.

Note: In the Generator model number the eighth character will be designated "R" or "F". "R" is used to indicate Radiographic units only and "F" indicates Radiographic and Fluoroscopic X-ray modes of operation.
The ninth character indicates the Generator output power level and the tenth place/position indicates the 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.

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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/AAMI ES60601-1:2005/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) Indico IQ X-ray generator is intended for use in stationary radiographic and fluoroscopic 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 console, an R&F 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.

6) 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
70084496	2016-07-06	Update to the CSA report to cover changes to the momentary current and nominal current for models identified in Part A, B and C.
2701600	Feb 24, 2014	Update to CSA Report 2556969 to cover new model VZW2949FH2-YY.
2644864	Jul 16, 2013	Update to Report 2556969 to cover new model VZW2558FB8YY
2627262	Jun 3, 2013	Update to Report to cover new model VZW2558FC8YY.
2556969	Sep 21, 2012	Original Certification to 60601-1 3rd Ed