Certificate of Compliance

Certificate: 2700412 **Master Contract:** 163059 (097383_C_000)

Project: 70084497 **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, Indico 100 Series, permanently connected, Models:

PART A)
80 kW Series:
- VZW2930RD2-YY: rated 400Vac, 3P, 50/60Hz, Rad.
- VZW2930RD3-YY: rated 480Vac, 3P, 50/60Hz, Rad.
- VZW2930FD2-YY: rated 400Vac, 3P, 50/60Hz, R/F.
- VZW2930FD3-YY: rated 480Vac, 3P, 50/60Hz, R/F.

PART B)
65 kW Series:
- VZW2930RC2-YY: rated 400Vac, 3P, 50/60Hz, Rad.
- VZW2930RC3-YY: rated 480Vac, 3P, 50/60Hz, Rad.
- VZW2930FC2-YY: rated 400Vac, 3P, 50/60Hz, R/F.
- VZW2930FC3-YY: rated 480Vac, 3P, 50/60Hz, R/F.

PART C)
50 kW Series:
- VZW2930RB2-YY: rated 400Vac, 3P, 50/60Hz, Rad.
- VZW2930RB3-YY: rated 480Vac, 3P, 50/60Hz, Rad.
- VZW2930FB2-YY: rated 400Vac, 3P, 50/60Hz, R/F.
- VZW2930FB3-YY: rated 480Vac, 3P, 50/60Hz, R/F.

PART D)
40 kW Series:
- VZW2930RE5-YY: rated 230Vac, 1P, 50/60Hz, Rad.
- VZW2930FE5-YY: rated 230Vac, 1P, 50/60Hz, R/F.
- VZW2930RE2-YY: rated 400Vac, 3P, 50/60Hz, Rad.
- VZW2930FE2-YY: rated 400Vac, 3P, 50/60Hz, R/F.
- VZW2930FE3-YY: rated 400/480Vac, 3P, 50/60Hz, R/F.

PART E)
32 kW Series:
- VZW2930RH5-YY: rated 230Vac, 1P, 50/60Hz, Rad.
- VZW2930RH2-YY: rated 400Vac, 3P, 50/60Hz, Rad.
- VZW2930FH2-YY: rated 400/480Vac, 3P, 50/60Hz, R/F.

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 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" to "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: 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
6. Environmental Conditions: Normal: 10-40°C, 20-80% rH (non-condensing), 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 - CORR.2)
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

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	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Corrigendum C1
ANSI/AAMI ES60601-1:2005 / A2:2010	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment A2

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

Subject to the following qualifications:

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

2. 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).

3. SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

4. 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.

5. 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
70084497	2016-07-06	Update to the CSA Report to cover optional kits: Indico 100 Generator Cooling Kit and ADR Option Cooling Kit.
2700412	Feb 13, 2014	Update to the report to cover alternate EMI filter for models indicated in Part B of the Report.
2531570	Jun 5, 2012	Evaluation to 60601-1 3rd Edition