



## CERTIFICATE

No. U8V 101556 0002 Rev. 00

Holder of Certificate: Communications & Power Industries

Canada Inc.

45 River Drive

Georgetown ON L7G 2J4

CANADA

Certification Mark:



Product: **General Medical Devices** 

Medical Electrical Component,

CMP150 High Frequency X-ray Generator

The product was voluntarily tested according to the relevant safety requirements noted above. It can be marked with the certification mark above. The mark must not be altered in any way. This product certification system operated by TÜV SÜD America Inc. most closely resembles system 3 as defined in ISO/IEC 17067. Certification is based on the TÜV SÜD "Testing and Certification Regulations". TÜV SÜD America Inc. is an OSHA recognized NRTL and a Standards Council of Canada accredited certification body.

Test report no.:

7169004756-000

Date,

2018-09-10

(Peter Keith)





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Model(s): VZW2564RNCA11-XX, VZW2565RNCA11-XX

> The suffix XX is between "00" and "99" and "AA to ZZ", and represents other hardware and software options (not affecting

safety)

Tested CAN/CSA-C22.2 No. 60601-2-54:2011

ANSI/AAMI ES60601-1:2005/A1:2012-08 excluding Clause 11.7, 12.2, according to:

CAN/CSA-C22.2 No. 60601-1:2014 excluding Clause 11.7, 12.2, 15.1,

14 and 17

101556

Production

Facility(ies):

Parameters: Rated Input Voltage: 100-240 Vac

> Rated Frequency: 50/60 Hz

Rated Input Current: 0.8A Nominal, 11-15A, Momentary

Protection Class:

## Conditions of Acceptability

- This equipment is certified as component power supply for use in X-Ray generator. Only MOOP is considered during the product investigation. The unit is not intended to come into access with the patient.
- 2. SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
- 3. Interconnection of this medical device with other medical devices, medical used systems or nonmedical devices shall be evaluated to the requirements of Clause 16 in the end use application.
- 4. Safety Risk Management: A risk management process complying with the requirements of standard ISO 14971 was inspected during the evaluation of this medical device and/or additional considerations were taken into account since the subject legacy medical device was evaluated to the previous edition of this standard.
- 5. During the evaluation of this medical device, the risk management decisions affecting the test requirements have been taken into consideration. Changes/Updates in risk management documents that affect the safety of this medical device during its lifecycle shall be communicated to the CSA Group as a condition for continued certification.
- 6. Optional console shall be located such that the probability of a connection to a PATIENT, either directly or through the body of the OPERATOR, through which a current exceeding the allowable TOUCH CURRENT could flow, is negligible in NORMAL USE. The instructions for use instruct the OPERATOR not to touch the relevant part and the PATIENT simultaneously shall be provided in the end use medical equipment.