



America

CERTIFICATE

No. QS6 101556 0014 Rev. 00

Certificate Holder:

**Communications & Power Industries
Canada Inc.**
45 River Drive
Georgetown ON L7G 2J4
CANADA

Certification Mark:



Scope of Certificate:

**Design, Manufacture, and Servicing of Medical X-Ray
High Voltage Power Supplies and Generators**

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

**Health Canada, USA FDA. See attached for listing of
specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 101556 0014 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:QS6_101556_0014_Rev_00)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F008239

Report No.:

7169015693

Effective Date:

2025-05-30

Expiry Date:

2027-09-09

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Date of Issue: 2025-06-02

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803

- 21 CFR Part 806

- 21 CFR Part 807 – Subparts A to D

- 21 CFR Part 820

Facility(ies):

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