

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 543468**
Issued To: **Communications & Power Industries
Canada Inc.
45 River Drive
Georgetown
Ontario
L7G 2J4
Canada**

In respect of:

The design and manufacture of Diagnostic X-Ray Generators and power supplies.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2008-11-14**

Date: **2019-02-14**

Expiry Date: **2023-03-12**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Communications & Power Industries International Inc. Hohenadlstraße 31 Ismaning 85737 Germany	EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
14 November 2008	7287518	First Issue
18 March 2013	7912261	Certificate Renewal Addition of CPI International, Germany as EU Representative
7 March 2018	8853541	Certificate Renewal. Deletion of Digital Imaging Systems from the Scope of certificate.
Current	7782106	Traceable to NB 0086

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