

# EC Certificate - Full Quality Assurance System

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

**No.** CE 697580  
Issued To: **Richardson Electronics**  
**40W267 Keslinger Road**  
**LaFox**  
**Illinois**  
**60147**  
**USA**

In respect of:

**The design and manufacture of x-ray tube housing assemblies for diagnostic radiology.**

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):



Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2019-08-23**

Date: **2019-08-23**

Expiry Date: **2024-05-26**

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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.

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## Supplementary Information to CE 697580

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NBOG Code	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
35618	ALTA750 - X-Ray Tube Housing Assembly	X-Ray Tube Housing Assemblies are designed to emit ionizing radiation and are intended to be used as a component of a CT system which is used for diagnostic and interventional X-Ray applications.

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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**

Richardson Electronics GmbH  
Raiffeisenstrasse 5,  
Donaueschingen  
78166  
Germany

**EU Representative**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 697580**  
 Date: **2019-08-23**  
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Date	Reference Number	Action
23 August 2019	9628209	First Issue
<b>Non-significant changes approved after the 26<sup>th</sup> May 2021 as per the Transitional Provisions of MDR Article 120.3</b>		
10 November 2022	3787855	Correction to Device Table to list the generic device group "X-Ray Tube Housing Assembly" rather than specific product names

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

10 November 2022

Richardson Electronics  
40W267 Keslinger Road  
LaFox  
Illinois  
60147  
USA

To whom it may concern,

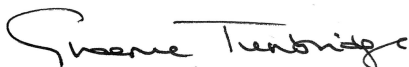
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

<b>Certificate</b>	<b>Directive and Annex</b>	<b>Reference Number</b>	<b>Changes approved</b>
CE 697580	93/42/EEC Annex II excluding Section 4	3787855	Correction to Device Table to list the generic device group "X-Ray Tube Housing Assembly" rather than specific products names, such as ALTA750 and ALTA750G

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge  
Senior Vice President, Medical Devices