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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Supplementary Information to CE 697580

Issued To:

Richardson Electronics
40W267 Keslinger Road
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NBOG Code	Device Name	Intended purpose per IFU
Class IIb		
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.

First Issued: **2019-08-23** Date: **2019-08-23** Expiry Date: **2024-05-26**

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By Royal Charter

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

List of Significant Subcontractors

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

Certificate No:	**CE 697580**
Date:	**2019-08-23**
Issued To:	**Richardson Electronics** **40W267 Keslinger Road** **LaFox** **Illinois** **60147** **USA**

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**

Issued To: **Richardson Electronics**
40W267 Keslinger Road
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Date	Reference Number	Action
23 August 2019	9628209	First Issue
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
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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10 November 2022

Richardson Electronics
40W267 Keslinger Road
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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 26th 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.

Certificate	Directive and Annex	Reference Number	Changes approved
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

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