

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
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.

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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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Certificate History

Certificate No: **CE 697580**
Date: **2019-08-23**
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Date	Reference Number	Action
Current	9628209	First Issue

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