

# EC Certificate - Full Quality Assurance System

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

**No.** CE 95048  
**Issued To:** Vision RT Ltd  
Dove House  
Arcadia Avenue  
London  
N3 2JU  
United Kingdom

In respect of:

**Design, manufacture and installation of 3D surface imaging systems for treatment planning, patient positioning and monitoring, including automated beam hold, respiratory gated imaging and treatment, in radiation therapy.**

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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **13 July 2005**

Date: **16 June 2015**

Expiry Date: **17 June 2020**

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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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## List of Significant Subcontractors

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

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Date: **16 June 2015**  
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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Carville Ltd Station Road Dorking Surrey RH4 1HQ United Kingdom	<b>Crucial Supplier</b>
Integrated Technologies Limited Viking House Ellingham Way Ashford Kent TN23 6NF United Kingdom	<b>Manufacture</b>
Tecnologie Avanzate TA s.r.l. Lungo Dora, 36B Torino (TO) 10153 Italy	<b>Final Inspection</b>

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**Subcontractor:**

**Service(s) supplied**

Vision RT Ltd  
Stanley House  
Old Brick Kiln  
Monk Sherborn Road  
Ramsdell  
Hampshire  
RG26 5PR  
United Kingdom

**Design  
Manufacture**

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# EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
13 July 2005	4676343	First issue
20 December 2007	7147508	Re-issue to extend scope to include automated beam hold and also respiratory gated imaging and treatment products. Also inclusion of subcontract manufacturer, Integrated Technologies Ltd and subcontract installer for final inspection, Technologie Avanzate TA S.r.l.
18 June 2010	7475398	Renewal to include change of address for business premises from Daws Lane, London NW7 to Arcadia Avenue London N3. No change to scope.
16 June 2015	8315368	Certificate renewal. Addition of Vision RT site in Ramsdell, UK. Change of address of significant subcontractor Technologie Avanzate TA S.r.l. Addition of Carville Ltd as a crucial supplier.