

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):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2005-07-13**

Date: **2018-07-05**

Expiry Date: **2020-07-12**

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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.

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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

Varian Medical Systems, Inc
3100 Hansen Way
Palo Alto
California
94303
USA

Installation

Vision RT Ltd
The Crescent
Jays Close
Viabes Industrial Estate
Basingstoke
Hampshire
RG22 4BS
UK

Design
Manufacture
Remanufacturing

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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.
07 June 2016	8523654	Re-issue due to: 1. Removal of subcontractors; Integrated Technologies Ltd, Carville Ltd and Technologie Avanzate TA S.r.l. 2. Addition of subcontractor; Varian Medical System Inc for installation. 3. Address change of Vision RT- Ramsdell from "Monk Sherborn Road" to "Monk Sherborne Road" due to typo

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		<p>4. Addition of 'Purchasing' and 'Refurbishment' activities to Vision RT- Ramsdell.</p> <p>5. Change in expiry to 12 July 2020 due to error during renewal.</p>
Current	8895086	Certificate reissue due to change of address of Vision RT Ltd from Stanley House, Old Brick Kiln, Monk Sherborne Road, Ramsdell to The Crescent, Jays Close, Viabes Industrial Estate, Basingstoke.