Manufacturer Evidence

Status : Approved

Certificate change history

Version 2: Accepted. Updated CE certificate provided. (Hooman Pour, 5/04/2016)

Date received :	24/03/2016
Certificate printed :	No
Variation to Evidence ID: DV-2014-MC-13597-1	

Notification details

Evidence identifier:	DV-2014-MC-13597-1
Submission identifier:	DM-2016-01660-1
Version number:	2
Sponsor's own reference:	Varian Medical Systems Inc

Sponsor details

Agent name:	[redacted]
Sponsor name:	Varian Medical Systems Australasia Pty Ltd
Contact details:	[redacted]

Certification details

Manufacturer name:	Varian Medical Systems Inc (United States Of America)[31699]
Manufacturer address as on certification:	3100 Hansen Way PALO ALTO CA 94304 United States Of America S [145152]
Type of product:	

○ This certification is to support an application for an in vitro diagnostic medical device (IVD)
● This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under:	Council Directive 93/42/EEC (MDD)
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Source of certification:	BSI Product Services [0086] Lookup
Certificate number:	CE01414
Certificate issue date: (dd/mm/yyyy)	08/03/2011
Certificate expiry date: (dd/mm/yyyy)	06/08/2016
Certificate re-issue date: (dd/mm/yyyy)	23/11/2015
Restrictions on scope:	

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.
Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

Attached documentation:

Attached documents	EC Certificate - CE 01414 Full Quality Assurance Certificate to 6th Augu Additional supporting documentation - Velocity_Purchase Statement.pdf

Supporting documents:			
#	Document Type	Description	Method

Related Active ARTG Entry Information:	
228953	Varian Medical Systems Australasia Pty Ltd - Radiology picture archiving and communication system ap software

History

CN=Hooman Pour/OU=TGA/O=Health

R16/281324 Document 6

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EC Certificate - Full Quality Assurance System

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

No. **CE 01414**

Issued To: **Varian Medical Systems, Inc.**
3100 Hansen Way
Palo Alto
California
94304
USA

In respect of:

The design and manufacture of linear accelerators for radiotherapy, radiotherapy simulators, high dose rate and pulse dose rate brachytherapy afterloader equipment and sterile brachytherapy needles, radiotherapy image acquisition, treatment planning systems and associated accessories.

Those aspects of Annex II related to metrology in the design and manufacture of the measurement ruler.

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: **11 September 1996** Date: **23 November 2015** Expiry Date: **06 August 2016**

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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EC Certificate - Full Quality Assurance System

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 01414**

Date: **23 November 2015**

Issued To: **Varian Medical Systems, Inc.**
3100 Hansen Way
Palo Alto
California
94304
USA

Subcontractor:	**Service(s) supplied**
Raumedic AG Hermann-Staudinger-Strasse 2 95233 Helmbrechts Germany	**Sterile Manufacture**
Teleflex Medical Europe Ltd. IDA Business and Technology Park Dublin Road, Athlone, Co. Westmeath Ireland	**Sterile Manufacture**
Varian Medical Systems Haan GmbH Bergische Strasse 16 42781 Haan Germany	**Design** **Manufacture**
Varian Medical Systems Imaging Laboratory GmbH Täfernstrasse 7 CH-5405 Baden-Dättwill Switzerland	**Design** **Manufacture**

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EC Certificate - Full Quality Assurance System

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 01414**
Date:	**23 November 2015**
Issued To:	**Varian Medical Systems, Inc.** **3100 Hansen Way** **Palo Alto** **California** **94304** **USA**

Subcontractor:	**Service(s) supplied**
Varian Medical Systems Inc. 501 Locust Avenue,Suite 1 Charlottesville Virginia 22902 USA	**Design** **Manufacture**
Varian Medical Systems UK Ltd Oncology House, Gatwick Road Crawley West Sussex RH10 9RG United Kingdom	**Design** **EU Representative** **Manufacture**
Varian Medical Systems, Inc. 1350 Spring Street Suite 275 Atlanta Georgia 30309 USA	**Design** **Manufacture**

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EC Certificate - Full Quality Assurance System

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 01414**

Date: **23 November 2015**

Issued To: **Varian Medical Systems, Inc.**
3100 Hansen Way
Palo Alto
California
94304
USA

Subcontractor:	**Service(s) supplied**
Varian Medical Systems, Inc. 911 Hansen Way Palo Alto California 94304 USA	**Design** **Manufacture**
Varian Medical Systems China Co., Ltd. 8 Yun Cheng Jie BDA Beijing 100176 China	**Manufacture**
Varian Medical Systems Finland OY Paciuksenkatu 21 Helsinki FIN-00270 Finland	**Design** **Manufacture**

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EC Certificate - Full Quality Assurance System

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 01414**
Date:	**23 November 2015**
Issued To:	**Varian Medical Systems, Inc.** **3100 Hansen Way** **Palo Alto** **California** **94304** **USA**

Subcontractor:	**Service(s) supplied**
Varian X-Ray Products 1678 South Pioneer Road Salt Lake City UT 84104 USA	**Design** **Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01414**

Date: **23 November 2015**

Issued To: **Varian Medical Systems, Inc.**
3100 Hansen Way
Palo Alto
California
94304
USA

Date	Reference Number	Action
11 September 1996	-	Initial Issue
11 June 1997	-	Addition of second site at Milpitas
24 August 1999	-	Change to scope to include electron applicators, wedge trays, multi-leaf collimators, operator interface and client server software
18 April 2000	-	Change to scope to include development and respiratory gating
03 September 2003	-	The following EC Annex II Quality Assurance Certificates were merged into this certificate: CE 01140, CE 01629 and CE 73830. The scope was modified to include radiotherapy simulators, high dose rate brachytherapy afterloader equipment, radiotheraphy image acquisition and radiotherapy treatment planning systems. Five year renewal.
24 October 2003	-	Addition of VMS Haan GmbH, Varian Medical Systems, Charlottesville, VA and Varian X-Ray Products as sub-contractors
08 April 2004	-	Addition of pulse dose rate brachytherapy afterloader equipment and sterile brachytherapy needles to scope. Additional sub-contractor, Ranfac Corporation for the manufacture of sterile brachytherapy needles, and change of company name at the Baden site.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01414**

Date: **23 November 2015**

Issued To: **Varian Medical Systems, Inc.**
3100 Hansen Way
Palo Alto
California
94304
USA

Date	Reference Number	Action
16 May 2005	4704567	Addition of sub-contractors 'Willy RÜSCH AG', 'Angiomed GmbH & Co. Medizintechnik KG.' for sterile manufacture. Addition of Varian site at '911 Hansen Way, Palo Alto' Change of address for Varian site 'Baden, Switzerland'
07 August 2006	4844323	Certificate Renewal
20 December 2006	4888718	Addition of Varian Medical Systems France as a subcontractor for design
12 December 2007	7145593	Addition of "Varian Medical Systems Beijing Co., Ltd." as manufacturing location
20 January 2009	7314525	Addition of "Raumedic AG, Germany" as a sterile manufacturing location, removal of "Angiomed GmbH & Co."
30 November 2010	7548454	Extension to scope to include Class I(m) measurement ruler. Addition of EU Representative Varian Medical Systems UK Limited.
04 August 2011	7717402	Certificate renewal. Removal of Varian Medical Systems, France as design subcontractor.

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01414**

Date: **23 November 2015**

Issued To: **Varian Medical Systems, Inc.**
3100 Hansen Way
Palo Alto
California
94304
USA

Date	Reference Number	Action
26 November 2012	7916711	Correction of subcontractor address from '3100 Hansen Way' to '911 Hansen Way'
23 November 2015	8348200	Change of address subcontractor Varian medical systems Inc to 501 locust Ave. Minor amendment of address subcontractor Varian systems Ltd to include building name. Addition of subcontractors Varian medical systems, Atlanta and Teleflex Medical Europe Ltd. Removal of subcontractors Ranfac Corporation and Willy Rusch.