EC Certificate - Full Quality Assurance System

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

No. **CE 95140**

Issued To: **Vital Images, Inc.**
5850 Opus Parkway
Suite 300
Minnetonka
Minnesota
55343
USA

In respect of:

The design and manufacture of software for medical imaging applications intended to allow visualization, analysis and communication of medical images.

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: **2005-08-12** Date: **2020-04-24** Expiry Date: **2024-05-26**

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Supplementary Information to CE 95140

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NBOG Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1111	Vitrea Advanced Visualization	N/A for IIa device
MD 1111	Vitrea View	N/A for IIa device

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By Royal Charter

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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**
Canon Medical Systems Corporation 1385, Shimoishigami Otawara-Shi Tochigi 324-8550 Japan	**Crucial Supplier**
MDSS (Medical Device Safety Service GmbH) Schiffgraben 41 30175 Hannover Germany	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 95140**

Date: **2020-04-24**

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Date	Reference Number	Action
12 August 2005		First Issue. Transfer from TUV PRODUCT SERVICE, Certificate No.: G2M.05.03.39815.004.
12 July 2010	7475400	Certificate renewal and the addition of MediMark as EU representative
13 November 2012	7903620	Certificate reissue due to the reclassification by manufacturer of some software for medical imaging applications from Class I with measuring function to Class IIa.
23 July 2015	8312538	Certificate renewal. Upgrade from Annex V to Annex II. Scope change: The design and manufacture of software for medical imaging applications intended to allow visualization, analysis and communication of medical images and those aspects of Annex II concerned with the metrological requirements of software for medical imaging applications. Change of EU representative details to 'Medical Device Safety Service (MDSS) GmbH, Schiffgraben 41 , 30175 Hannover, Germany '. Addition of 'Toshiba Medical Systems Corporation (TMSC), Tochigi, Japan' and 'Toshiba Medical Visualization Systems Europe, Ltd (TMVS), Edinburgh, UK' as crucial suppliers.

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Date	Reference Number	Action
05 October 2017	8732840	Reduction of scope to remove reference of 'those aspects of Annex II concerned with the metrological requirements of software for medical imaging applications.
16 May 2018	8939335	Changes to address details of crucial suppliers Toshiba Medical System Corporation and Toshiba Medical Visualization Systems Europe, Ltd to Canon Medical Systems Corporation and Canon Medical Research Europe Ltd. Update to address details of Canon Medical Research Europe Ltd.
21 February 2019	7781897	Traceable to NB 0086.
24 April 2020	9768648	Certificate renewal. Removal of crucial supplier Canon Medical Research Europe Ltd. Correct the EU representative address from "Hanover to "Hannover". Addition of device table.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
26 April 2022	3621611	Organisation name changed from 'Vital Images, Inc.' to 'Canon Medical Informatics, Inc.'

Inspiring trust for a more resilient world.

26 April 2022

Canon Medical Informatics, Inc.
5850 Opus Parkway
Suite 300
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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 95140	93/42/EEC Annex II excluding Section 4	3621611	Organisation name changed from 'Vital Images, Inc.' to 'Canon Medical Informatics, Inc.'

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

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl