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):

Albert Roossien, Regulatory Lead

First Issued: **2005-08-12** Date: **2019-02-21** Expiry Date: **2020-08-10**

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By Royal Charter

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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:

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Date:	**2019-02-21**
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Subcontractor:	**Service(s) supplied**
Canon Medical Research Europe Ltd Bonnington Bond 2 Anderson Place Edinburgh EH6 5NP United Kingdom	**Crucial Supplier**
Canon Medical Systems Corporation 1385, Shimoishigami Otawara-Shi Tochigi 324-8550 Japan	**Crucial Supplier**
MDSS (Medical Device Safety Service GmbH) Schiffgraben 41 30175 Hanover Germany	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

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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.

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Date	Reference Number	Action
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.
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.

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Date	Reference Number	Action
Current	7781897	Traceable to NB 0086.