By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 649468**

Issued To: **iCAD, Inc.**
98 Spit Brook Road
Suite 100
Nashua
New Hampshire
03062
USA

In respect of:

Design and manufacture of medical devices for the digitization and image processing of radiographic and other film and computer-aided detection of physiological targets in digitized and digitally captured 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: **2016-03-11** Date: **2021-03-25** Expiry Date: **2024-05-26**

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Supplementary Information to CE 649468

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD1111	Software – M-Vu CAD System	N/A
MD1111	Software – PowerLook Density Assessment	N/A
MD1111	Software – ProFound AI	N/A

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List of Significant Subcontractors

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

Certificate No:	**CE 649468**
Date:	**2021-03-25**
Issued To:	**iCAD, Inc.** **98 Spit Brook Road** **Suite 100** **Nashua** **New Hampshire** **03062** **USA**

Subcontractor:	**Service(s) supplied**
iCAD Inc 4 Townsend West, Suite 9 Nashua New Hampshire 03063 USA	**Manufacture**
Medical Device Safety Service (MDSS) Schiffgraben 41 30175 Hannover Germany	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 649468**
Date: **2021-03-25**
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Date	Reference Number	Action
11 March 2016	8481830	First issue. The devices were previously CE-marked by VuCOMP, Inc. under certificate CE 597505.
08 February 2017	8622974	Change of legal manufacturer's address from 2500 N. Dallas Parkway, Suite 510, Plano, Texas 75093, USA to 4 Townsend West, Suite 9, Nashua, New Hampshire 03063, USA.
08 January 2018	8844189	Reissue due to scope update by transfer of EC certification from AMTAK (Intertek) to BSI and change of EU Representative.
20 February 2019	8707143	Traceable to NB 0086.
18 July 2019	9775511	Renewal of certificate and addition of product table.
Current	3316085	Re-issue for the update of the device table to reflect the rebranding of the PowerLook Tomo Detection software, now named ProFound AI Software.