

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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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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Supplementary Information to CE 649468

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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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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

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

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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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Certificate History

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USA

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.

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