

EC Certificate - Full Quality Assurance System

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

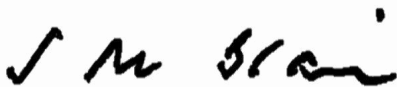
No. CE 649468
Issued To: **iCAD, Inc.**
98 Spit Brook Road
Suite 100
Nashua
New Hampshire
03062
USA

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2016-03-11**

Date: **2018-01-08**

Expiry Date: **2019-07-29**

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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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List of Significant Subcontractors

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

Certificate No: **CE 649468**
Date: **2018-01-08**
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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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EC Certificate - Full Quality Assurance System 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.
Current	8844189	Reissue due to scope update by transfer of EC certification from AMTAK (Intertek) to BSI and change of EU Representative.