

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 560107****Issued To:**

**iCRco, Inc.
26 Coromar Drive
Goleta
California
93117
USA**

In respect of:

The Manufacture of digital radiography (DR) and Computed Radiography (CR) image readers and image management software (PACS)

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **24 May 2010**

Date: **20 May 2015**

Expiry Date: **23 May 2020**

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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 560107**
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26 Coromar Drive
Goleta
California
93117
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Subcontractor:

Service(s) supplied

iCRco, Europe GmbH
 Paderborner Str.21
 Dortmund
 44143
 Germany

EU Representative

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Certificate History

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Date: **20 May 2015**
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Date	Reference Number	Action
24 May 2010	7494142	First issue
13 September 2011	7727696	Reissue following the change of EU Representative address from Munich, Germany to Dortmund, Germany.
27 February 2013	7901157	Addition of iCRco R&D Facility, 26 Coromar Drive, Goleta, CA 93117
20 May 2015	8266645	Certificate renewal and address change of the legal manufacturer from 2580 West 237 th Street, Torrance, CA 90505 to iCRco, Inc., 26 Coromar Drive, Goleta, CA 93117, USA and Goleta location has been removed as a significant subcontractor

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