

EC Certificate - Full Quality Assurance System

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

No. CE 539277
Issued To: **Circle Cardiovascular Imaging Inc.**
Suite 250, 815 8th Avenue SW
Calgary
Alberta
T2P 3P2
Canada

In respect of:

Design and manufacture of multiplatform Cardiovascular Magnetic Resonance (MR) and Computed Tomography (CT) Imaging software applications in DICOM standard format.

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **28 November 2008**

Date: **12 January 2017**

Expiry Date: **27 November 2018**

...making excellence a habit.™

Page 1 of 1

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.

EC Certificate - Full Quality Assurance System

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:

Certificate No: **CE 539277**
Date: **12 January 2017**
Issued To: **Circle Cardiovascular Imaging Inc.
Suite 250, 815 8th Avenue SW
Calgary
Alberta
T2P 3P2
Canada**

Subcontractor:

Service(s) supplied

Philipp Barckow
Ravenweg 9
14163 Berlin
Germany

EU Representative

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 539277**
 Date: **12 January 2017**
 Issued To: **Circle Cardiovascular Imaging Inc.
 Suite 250, 815 8th Avenue SW
 Calgary
 Alberta
 T2P 3P2
 Canada**

Date	Reference Number	Action
28 November 2008	7228206	First issue.
12 January 2009	7303375	Certificate reissue to reflect the company address change
15 November 2013	8026086	Certificate renewal, change the manufacturer address to "Suite 250, 815 8th Avenue SW, Calgary, Alberta", and the addition of "Philipp Barckow" as a significant subcontractor for EU representative.
12 January 2017	8574943	Extension of scope to include Computed Tomography (CT)

...making excellence a habit.™

Page 1 of 1

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.