

EC Certificate - Full Quality Assurance System

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

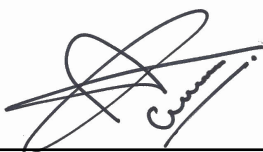
No. CE 539277
Issued To: **Circle Cardiovascular Imaging Inc.**
Suite 1100, 800 5th Avenue SW
Calgary
Alberta
T2P 3T6
Canada

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2008-11-28**

Date: **2019-02-11**

Expiry Date: **2023-11-27**

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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.

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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Date: **2019-02-11**
Issued To: **Circle Cardiovascular Imaging Inc.
Suite 1100, 800 5th Avenue SW
Calgary
Alberta
T2P 3T6
Canada**

Subcontractor:

Service(s) supplied

Philipp Barckow
Ravenweg 9
14163 Berlin
Germany

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 539277**
 Date: **2019-02-11**
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 T2P 3T6
 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).
10 November 2017	8791532	Certificate reissue to reflect the company address change from Current address: Suite 250, 815 8th Avenue SW, Calgary AB T2P 3P2, Canada to New address: Suite 1100, 800 5th Avenue SW Calgary AB T2P 3T6, Canada.
09 November 2018	8992102	Certificate renewal.
Current	7782055	Traceable to NB 0086.

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Page 1 of 1

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