By Royal Charter

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2008-11-28** Date: **2018-11-09** Expiry Date: **2023-11-27**

...making excellence a habit.™

By Royal Charter

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:	**2018-11-09**
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**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 539277**

Date: **2018-11-09**

Issued To: **Circle Cardiovascular Imaging Inc.**
Suite 1100, 800 5th Avenue SW
Calgary
Alberta
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.
Current	8992102	Certificate renewal.