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):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2008-11-28** Date: **2019-02-11** Expiry Date: **2023-11-27**

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By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 539277**
Date: **2019-02-11**
Issued To: **Circle Cardiovascular Imaging Inc.**
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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.
11 February 2019	7782055	Traceable to NB 0086.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
28 March 2023	3892594	Change of EU Representative Removal of subcontractor page

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28 March 2023

Circle Cardiovascular Imaging Inc.
Suite 1100, 800 5th Avenue SW
Calgary
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 539277	93/42/EEC Annex II excluding Section 4	3892594	Change of EU Representative Removal of subcontractor page

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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