

# bsi.



## Certificate

# Full Quality Assurance



**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 Imaging software applications in DICOM standard format**

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

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

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Gary Fenton, Global Assurance Director

First Issued: **28 Nov 2008**

Date: **15 Nov 2013**

Expiration Date: **27 Nov 2018**

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*Conditions of Approval*

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 539277**  
Date: **15 Nov 2013**  
Issued to: **Circle Cardiovascular Imaging Inc.**  
**Calgary**  
**Canada**

**Subcontractor**

Philipp Barckow  
Ravenweg 9  
14163 Berlin  
Germany

**Service(s) supplied**

EU Representative



## History of Quality Assurance Certificate

**Certificate No:** CE 539277  
**Issue Date:** 15 Nov 2013  
**Issued to:** Circle Cardiovascular Imaging Inc.  
 Calgary  
 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.