

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Circle Cardiovascular Imaging Inc.  
Suite 1100, 800 5th Avenue SW  
Calgary  
Alberta  
T2P 3T6  
Canada

Facility ID Number: F000125

Holds Certificate No:

**MDSAP 689664**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and manufacture of vendor independent multiplatform Cardiovascular Magnetic resonance (MR) and Computed Tomography (CT) imaging software applications in DICOM standard format for use by medical professionals.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-03-20

Effective Date: 2022-08-22

Expiry Date: 2024-08-30



BSI Group America Inc. is an MDSAP recognised auditing organization

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