

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

DUNS Number: 24-802-8578

Holds certificate No:

MDSAP 689664

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - 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:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-03-20

Effective Date: 2019-03-20

Expiry date: 2021-08-30

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