



Certificate Number US20/819944119

The quality management system of

# Circle Neurovascular Imaging Inc

Suite 1100 800 5th Avenue SW, Calgary, Alberta T2P 3T6, Canada

Facility identification number : F005014

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

## MDSAP(ISO 13485:2016)

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

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

United States:

21 CFR 820/ 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

**Design, manufacture and installation of Computed Tomography (CT) imaging software applications for processing of DICOM standard format head CT images.**

This certificate is valid from

Effective Date: 2021-12-01 until Expiry Date: 2023-11-08 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2023-10-29

Issue 2. Certified since 2020-11-09

Authorised by LHenderson  
Business Manager

SGS United Kingdom Ltd

Rosmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

+44 (0)151 3506666 www.sgs.com

SGS United Kingdom Ltd is an MDSAP authorised auditing organization

SGS MDSAP 1116

Page 1 of 1



This document is a Web version of SGS certificate for electronic use exclusively. It shall only be available by clicking on SGS Certification Mark which has been posted on Your website. It shall not be printed in anyway. This document is copyright protected. No content or appearance may be reproduced without the express written permission of SGS. Any misuse, alteration, forgery or falsification is unlawful.