

EC Certificate Full Quality Assurance System:
Certificate US21/819944332

The management system of

Circle Neurovascular Imaging Inc

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 23 April 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 23 April 2021.

Certification is based on reports numbered WW/MC 616127

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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Circle Neurovascular Imaging Inc

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

StrokeSENS is a standalone software package and notification tool. The software allows for viewing and processing CT images and outputs results, and parametric maps related to tissue characteristics like ischemia, blood flow (perfusion) and blood volume that are written back to the source DICOM. Following such analysis, the software automatically sends the results of analysis to a preconfigured destination point. The software allows for repeated use and continuous processing of data and can be deployed on a supportive infrastructure that meets the minimum system requirements.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

