



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

KD & A Pty Ltd

for approval to supply

KD & A Pty Ltd - X-ray system, diagnostic, computed tomography, application program software

ARTG Identifier	380409
ARTG Start Date	8/12/2021
Product Category	Medical Device Included Class IIb
GMDN	40867
GMDN Term	X-ray system, diagnostic, computed tomography, application program software
Intended Purpose	<p>StrokeSENS is a decision-aid software package to be used by clinicians to perform image processing, analysis, viewing and communication of computed tomography (CT) scans of the brain in patients with suspected acute stroke. Data and images are acquired through DICOM-compliant imaging devices prior to processing and analysis in StrokeSENS.</p> <p>The StrokeSENS software provides analysis capabilities for imaging datasets acquired with standard CT imaging and contrast-enhanced CT Angiography (CTA) modalities. Analysis of non-contrast CT images is provided by the StrokeSENS ASPECTS module, which includes assessment of regions with suspected acute ischemic tissue (ie. ASPECTS scoring). Analysis of contrast-enhanced CT images is provided by the StrokeSENS LVO module, which includes automated detection of suspected large vessel occlusion (LVO).</p>

Manufacturer Details	Address	Certificate number(s)
Circle Neurovascular Imaging Inc	Suite 1100 800 5th Avenue SW Calgary , Alberta , T2 P 3T6 Canada	DV-2021-MC-24258-1

ARTG Standard Conditions

The above Medical Device Included Class IIb has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

- 1. X-ray system, diagnostic, computed tomography, application program software**

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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