



Australian Government

Department of Health and Aged Care
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	381253
ARTG Start Date	22/12/2021
Product Category	Medical Device Included Class IIa
GMDN	40867
GMDN Term	X-ray system, diagnostic, computed tomography, application program software
Intended Purpose	<p>TruPlan enables visualization and measurement of structures of the heart and vessels for:</p> <ul style="list-style-type: none">· Pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure· Post-procedural evaluation for the LAAC procedure <p>To facilitate the above, TruPlan provides general functionality such as:</p> <ul style="list-style-type: none">· Segmentation of cardiovascular structures· Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR· Simulation of TEE views, ICE views, and fluoroscopic rendering· Measurement and annotation tools· Reporting tools <p>TruPlan's intended patient population is comprised of adult patients.</p>

Manufacturer Details	Address	Certificate number(s)
Circle Cardiovascular Imaging Inc	Western Candian Place - North Tower Suite 1800 707 8th Avenue SW Calgary , Alberta , T2P 1H5 Canada	DV-2021-MC-17786-1

ARTG Standard Conditions

The above Medical Device Included Class IIa 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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