



Australian Government

Department of Health, Disability and Ageing

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**

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

Manufacturer Details	Address	Certificate number(s)
Circle Cardiovascular Imaging Inc	Western Canadian 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.

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