



**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**

<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>	TruPlan enables visualization and measurement of structures of the heart and vessels for pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure. To facilitate the above, TruPlan provides general functionality such as: - Segmentation of cardiovascular structures. - Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR. - Stimulation of TEE views, ICE views, and fluoroscopic rendering - Measurement and annotation tools Reporting tools

<b>Manufacturer Details</b>	<b>Address</b>	<b>Certificate number(s)</b>
Circle Cardiovascular Imaging Inc	Suite 1100 800 5th Avenue SW Calgary , Alberta , T2 P 3T6 Canada	DV-2021-MC-25713-1

### **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.