



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 - MRI system, application program software

ARTG Identifier	177785
ARTG Start Date	24/11/2010
Product Category	Medical Device Included Class IIa
GMDN	40872
GMDN Term	MRI system, application program software
Intended Purpose	The device is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) and computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format.

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. MRI system, application program software

Product Specific Conditions

- No specific conditions have been recorded against this entry.