Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Market Access Australia Pty Ltd

for approval to supply

Market Access Australia 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	cmr42 is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables: · Import and Export of Cardiac MR Images in DICOM format. · Qualitative analysis of cardiac MR images using display functionality such as panning, windowing, zooming, scrolling through series/slices and phases. · Display of 3D data and 4D cine animation of multi-phase 3D data including multiplanar reformatting · Quantitative measurement of the heart and adjacent vessels in cardiac MR images, specifically distance, area, volume, mass, flow velocities and pressure gradients. · Area and volume measurements for measuring LV function and derived parameter in long axis and short axis cardiac MR images. · Flow quantifications based on velocity encoded images. · Tissue characterization of late and early enhancement studies by quantifying signal intensity changes. · T2* analysis of gradient echo sequences · T1 mapping by assessing T1 Relaxation times of images with different Times of Inversions · Perfusion analysis of rest and intervention images It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. cmr42 is a software application that can be used as a stand-alone product or in a networked environment. The target population for the cmr42 is not restricted, however the image acquisition by a cardiac magnetic resonance scanner may limit the use of the device for certain sectors of the general public. cmr42 shall not be used to view or analyze images of any part of the body except the cardiac magnetic resonance images acquired from a cardiovascular magnetic resonance scanner.

Manufacturer Details	Address	Certificate number(s)
Circle Cardiovascular Imaging Inc	Suite 250 815 8th Avenue SW Calgary, Alberta, T2P 3P2	DV-2013-MC-19654-1

Manufacturer Details	Address	Certificate number(s)
	Canada	

ARTG Standard Conditions

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

- The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.,
- The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.,
- For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.,
- Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.,
- The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.,
- It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year. For orthopaedic implant prosthesis that have been re-classified from Class IIb to Class III medical devices, annual report information must be submitted if the device meets either of the following criteria: I.The device was subject to a TGA application audit based on revision rate when the device transitioned from Class IIb to Class III; and/or II.No devices were supplied to the Australian marketplace before 30 June 2012. As per the standard automatic condition, annual reports should be submitted each year for the first three years of inclusion as a Class III medical device on the ARTG.,
- Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.,
- A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Products Covered by This Entry

1. MRI system, application program software

Product Specific Conditions

No specific conditions have been recorded against this entry.