



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	214959	CardioCel - Cardiovascular Patch
ARTG entry for	Medical Device Included (Export Only) Class 1	
Sponsor	Admedus Regen Pty Ltd	
Postal Address	26 Harris Road, Malaga, WA, 6090 Australia	
ARTG Start Date	23/09/2013	
Product Category	Medical Device Class 1	
Status	Active	
Approval Area	Medical Devices	

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.

Manufacturers

Name	Address
Anteris Aus Operations Pty Ltd	26 Harris Road Malaga, WA, 6090 Australia

Products

1 . Cardiovascular Patch

Product Type	Single Device Product	Effective Date	23/09/2013
GMDN	35273 Cardiovascular patch, animal-derived		
Intended Purpose	CardioCel is indicated for use in pericardial closure and the repair of cardiac and vascular defects including intracardiac defects; septal defects, valve and annulus repair; great vessel reconstruction, peripheral vascular reconstruction and suture line buttressing		

Specific Conditions

No Specific Conditions included on Record

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