



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 169241 AA-Med Pty Ltd - Glucose monitoring system, in vivo

ARTG entry for Medical Device Included Class IIb
Sponsor AA-Med Pty Ltd
Postal Address Suite 4 Level 10 1 Chandos Street, St Leonards, NSW, 2065
Australia
ARTG Start Date 19/02/2010
Product Category Medical Device Class IIb
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
Dexcom Inc	6340 Sequence Drive San Diego, California, 92121 United States Of America

Products

1 . Glucose monitoring system, in vivo

Product Type	Medical device system	Effective Date	19/02/2010
GMDN	44611 Invasive interstitial-fluid glucose monitoring system		
Intended Purpose	A medical device used to continuously measure and record glucose concentrations in diabetic patients.		

Specific Conditions

No Specific Conditions included on Record

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