



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 267893 W9 Pty Ltd - Applicator, dental, <specify>

ARTG entry for Medical Device Included Class 1
Sponsor W9 Pty Ltd
Postal Address 1/27-29 Salisbury Road, HORNSBY, NSW, 2077
Australia
ARTG Start Date 27/01/2016
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
Great Plains Dental Products Inc	115 W C Avenue Kingman, KS, 67068-1314 United States Of America

Products

1 . Applicator, dental, <specify>

Product Type	Effective Date
Single Device Product	27/01/2016

GMDN 45051 Applicator, dental, <specify>
Intended Purpose A dental device used for the application of dental materials in the patient's mouth. This is a single-use device.

Specific Conditions

No Specific Conditions included on Record

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