



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	174193	W9 Pty Ltd - Tray, impression, dental
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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	26/07/2010
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
Astek Innovations Ltd	Astek House Atlantic Street Altrincham, Cheshire, WA14 5DH United Kingdom

Products

1 . Tray, impression, dental

Product Type	Single Device Product	Effective Date	26/07/2010
GMDN	16350 Tray, impression, dental		
Intended Purpose	A tray designed to support impression material used to take impressions of the mouth.		

Specific Conditions

No Specific Conditions included on Record

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