



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 112643 Unident Pty Ltd - Dental material, <specify>

ARTG entry for Medical Device Included Class 1

Sponsor Unident Pty Ltd

Postal Address PO Box 2095, WERRIBEE, VIC, 3030
Australia

ARTG Start Date 20/10/2004

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
Unident Pty Ltd	71 Riverside Avenue WERRIBEE, VIC, 3030 Australia

Products

1 . Dental material, <specify>

Product Type	Effective Date
Single Device Product	20/10/2004

GMDN 40592 Dental material, <specify>

Intended Purpose This is a thermoformal plastic sheet that is used to model and fabricate PVC splint material, PETG Splint material, temporary dental protheses, temporary crown and bridge, soft EVA (mouthguards) and hips base and custom trays that are placed in a patients mouth on a tempoary basis.

Specific Conditions

No Specific Conditions included on Record

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