



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 113957 Sportsguard Pty Ltd - Dental material, <specify>

ARTG entry for Medical Device Included Class 1

Sponsor Sportsguard Pty Ltd

Postal Address PO Box 111, FITZROY, VIC, 3065
Australia

ARTG Start Date 1/11/2004

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
Sportsguard Pty Ltd	82 Bell Street FITZROY, VIC, 3065 Australia

Products

1 . Dental material, <specify>

Product Type	Effective Date
Single Device Product	1/11/2004

GMDN 40592 Dental material, <specify>

Intended Purpose This is a thermoformal plastic sheet that is used to prefabricate PVC Splints, PETG splints, Dental Prostheses, Soft EVA (Mouthguards and splints) and HIPS base plates and custome trays.

Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary