



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 442053 Durodent Holdings Pty Ltd - Impression material, dental, silicone

ARTG entry for Medical Device Included Class IIa
Sponsor Durodent Holdings Pty Ltd
Postal Address PO Box 972, Bayswater, VIC, 3153
Australia
ARTG Start Date 22/02/2024
Product Category Medical Device Class IIa
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
Zhermack SPA	Via Bovazecchino 100 45021 Badia Polesine, , Italy

Products

1 . Impression material, dental, silicone

Product Type	Single Device Product	Effective Date	22/02/2024
GMDN	35866 Impression material, dental, silicone		
Intended Purpose	Dental impression materials that is a Elastomeric material based on polysiloxane capable of reacting to form a rubber-like material suitable for taking impressions.		

Specific Conditions

No Specific Conditions included on Record

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