



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Durodent Holdings Pty Ltd

for approval to supply

Durodent Holdings Pty Ltd - Impression material, dental, silicone

| | |
|-------------------------|--|
| ARTG Identifier | 313933 |
| ARTG Start date | 5/02/2019 |
| Product Category | Medical Device Included Class 1 |
| GMDN | 35866 |
| GMDN Term | 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. |

| Manufacturer Details | Address | Certificate number(s) |
|----------------------|---|-----------------------|
| Zhermack SPA | Via Bovazecchino 100 45021 Badia Polesine, , Italy | |

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Impression material, dental, silicone

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 313933
ARTG Start Date: 5/02/2019