



**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

<b>ARTG Identifier</b>	303821
<b>ARTG Start date</b>	2/06/2018
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	35866
<b>GMDN Term</b>	Impression material, dental, silicone
<b>Intended Purpose</b>	A range of Dental Impression and Bite Registration materials that is based on silicone materials including Polysiloxane / Vinyl Polysiloxane (includes Bite Registration, Mouth Putty, VPS etc) which forms a rubber-like material suitable for taking dental impressions of the teeth and gums. Used in dentistry to take impressions inside the mouth, i.e to create a reverse or negative model of the teeth and/or tissues inside the mouth, for the purposes of denture, crown & bridge or other dental prosthetic fabrication. Includes various delivery forms in cartridges, tubes and hand mixed mouth putty.

Manufacturer Details	Address	Certificate number(s)
Detax GmbH Co KG	Carl-Zeiss-Strasse 4 Ettingen, , 76275 Germany	

### 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  
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