



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 - Denture reliner, soft

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|-------------------------|--|
| ARTG Identifier | 303302 |
| ARTG Start date | 22/05/2018 |
| Product Category | Medical Device Included Class 1 |
| GMDN | 17610 |
| GMDN Term | Denture reliner, soft |
| Intended Purpose | Permanent Soft Relining denture material range used to cushion the underside of a denture to enable the denture to sit firmly in the mouth of patients. Whether being used chairside or in laboratory. Maybe used with a primer and/or adhesive / gloss to help smooth and seal these silicone based denture relining material. Self cure and heat cure. |

| 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. Denture reliner, soft

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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