



Australian Government

Department of Health and Aged Care
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, elastic, long-term

ARTG Identifier	412653
ARTG Start Date	5/07/2023
Product Category	Medical Device Included Class IIa
GMDN	34770
GMDN Term	Denture reliner, elastic, long-term
Intended Purpose	Intended Use: Definitive direct and indirect / chairside relining of dental prostheses Intended Users: Dental Professional / Dentist / Dental Technician Heat curing and self curing silicone, permanently soft relining materials, suitable for denture plastics based on (meth)acrylate / PMMA-based plastic materials. Maybe used with a primer and/or adhesive / gloss to help smooth and seal silicone based denture relining material.

Manufacturer Details	Address	Certificate number(s)
Detax GmbH	Carl-Zeiss-Strass 4 , Ettlingen , 76275 Germany	DV-2023-MC-15532-1

ARTG Standard Conditions

The above Medical Device Included Class IIa 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, elastic, long-term

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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