



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 sealing agent

ARTG Identifier	414490
ARTG Start Date	25/07/2023
Product Category	Medical Device Included Class IIa
GMDN	63589
GMDN Term	Denture reliner sealing agent
Intended Purpose	Intended use: Silicone gloss varnish for definitive silicone relinings Indication: Silicone-based gloss varnish for sealing and smoothing of Permaliner, Molloplast B & mollosil relinings Patient Target Group: Persons being treated in the context of a dental procedure. Intended Users: Dental Professional / Dentist / Dental Technician

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 sealing agent

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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