



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 - Dental prosthesis-component adhesive

ARTG Identifier	414836
ARTG Start Date	28/07/2023
Product Category	Medical Device Included Class IIa
GMDN	63626
GMDN Term	Dental prosthesis-component adhesive
Intended Purpose	Intended Use: Adhesives for denture relinings Indication: Adhesive optimizes the bond strength between relining material and polymerised acrylics. The chemical bond between acrylic and relining material is established by the adhesives. 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. Dental prosthesis-component adhesive

### Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
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