



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 - Dental material, modelling, polymer based

ARTG Identifier	303860
ARTG Start date	4/06/2018
Product Category	Medical Device Included Class 1
GMDN	34811
GMDN Term	Dental material, modelling, polymer based
Intended Purpose	Light curing liquid based polymer resin materials that is intended to be used as a 3D printing liquid for the manufacture and fabrication of dental devices such as surgical guides, splints, orthodontic models, retainers, special trays, aligners and any other device required. These devices maybe placed in the mouth for short term use.

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. Dental material, modelling, polymer based

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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