



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 prosthesis fabrication material,
polymer**

ARTG Identifier	297155
ARTG Start date	4/12/2017
Product Category	Medical Device Included Class IIa
GMDN	62816
GMDN Term	Dental prosthesis fabrication material, polymer
Intended Purpose	Polymer based dental materials (cold curing, self curing, light curing or heat curing) used in a dental laboratory for the manual or CAD/CAM milling fabrication, repair, rebasing or relining of full and partial dentures including implant overdentures, denture bases, splints, artificial teeth or other dental appliances.

Manufacturer Details	Address	Certificate number(s)
AcrylX GmbH	Rosbacher Strasse 14b , Rosbach, 61191 Germany	DV-2017-MC-18738-1

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 fabrication material, polymer

Product Specific Conditions

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Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

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