



**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**

<b>ARTG Identifier</b>	297155
<b>ARTG Start date</b>	4/12/2017
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	62816
<b>GMDN Term</b>	Dental prosthesis fabrication material, polymer
<b>Intended Purpose</b>	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

.

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

ARTG Identifier: 297155  
ARTG Start Date: 4/12/2017