



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 articulation liquid

<b>ARTG Identifier</b>	311411
<b>ARTG Start date</b>	12/11/2018
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	17844
<b>GMDN Term</b>	Dental articulation liquid
<b>Intended Purpose</b>	A range of pressure indicating material used to locate areas of denture or removable dental device discomfort in the patients mouth. Used for seating crowns, bridges, full dentures, immediate dentures and partial dentures.

Manufacturer Details	Address	Certificate number(s)
Keystone Industries	52 West King Street Myerstown , PA, 17067 United States Of America	

### 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 articulation liquid

### Product Specific Conditions

No specific conditions have been recorded against this entry.

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: 311411  
ARTG Start Date: 12/11/2018