



Australian Register of Therapeutic Goods Certificate

Issued to

Durodent Holdings Pty Ltd

for approval to supply

Durodent Holdings Pty Ltd - Impression material, dental, silicone

ARTG Identifier	313933
ARTG Start date	5/02/2019
Product Category	Medical Device Included Class 1
GMDN	35866
GMDN Term	Impression material, dental, silicone
Intended Purpose	Dental impression materials that is a Elastomeric material based on polysiloxane capable of reacting to form a rubber-like material suitable for taking impressions.

Manufacturer Details	Address	Certificate number(s)
Zhermack SPA	Via Bovazecchino 100 45021 Badia Polesine, , Italy	

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. Impression material, dental, silicone

Product Specific Conditions

No specific conditions have been recorded against this entry.