



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 - Impression material, dental, alginate

ARTG Identifier	313932
ARTG Start date	5/02/2019
Product Category	Medical Device Included Class 1
GMDN	35863
GMDN Term	Impression material, dental, alginate
Intended Purpose	Material used in dentistry containing an alginate as essential gel-forming ingredient, which after mixing with water, is capable of reacting to form a material suitable for taking dental impressions of the teeth and gums

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, alginate

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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