



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

ARTG Identifier: 313932
ARTG Start Date: 5/02/2019