



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 impression material preparation dispensing utensil

ARTG Identifier	385941
ARTG Start Date	21/03/2022
Product Category	Medical Device Included Class 1
GMDN	65886
GMDN Term	Dental impression material preparation dispensing utensil
Intended Purpose	A hand-held manual device intended for portioning/measuring and dispensing dental impression materials/components (e.g., alginate, silicone, water) at predefined volumes during impression material preparation; it is not intended for dispensing into the mouth (i.e., not an applicator or tray). It is typically in the form of a spoon and/or cup with a pre-defined volume or with portion-graduated markings. This is a reusable device.

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. Dental impression material preparation dispensing utensil

Product Specific Conditions

No specific conditions have been recorded against this entry.