



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 - Denture trial fabrication wax

ARTG Identifier	391238
ARTG Start Date	24/06/2022
Product Category	Medical Device Included Class 1
GMDN	63983
GMDN Term	Denture trial fabrication wax
Intended Purpose	A material made primarily of wax, intended to be used in the dental laboratory / denture clinic to design and manufacture a trial denture base before producing the final device for the patient. It is commonly supplied in sheets and may be referred to as denture sheet wax or dental modelling wax. This is a single-patient, reusable device. It is temporarily placed inside the oral cavity to check fit and function. This product is manufactured in various colour shades and different working properties.

Manufacturer Details	Address	Certificate number(s)
Metrodent Limited	Lowergate Works Lowergate Paddock Huddersfield , UK , H D3 4EP United Kingdom	

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. Denture trial fabrication wax

Product Specific Conditions

No specific conditions have been recorded against this entry.