



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Durodent Holdings Pty Ltd

for approval to supply

Durodent Holdings Pty Ltd - Tray, impression, dental

ARTG Identifier	411019
ARTG Start Date	22/06/2023
Product Category	Medical Device Included Class 1
GMDN	16350
GMDN Term	Tray, impression, dental
Intended Purpose	Intended Use: Resin for dental 3D printing. Light-curing resin based on (meth)acrylate, biocompatible, for the generative fabrication of individual and functional impression trays and base plates for 3D resin printers. Intended Users: Dentist, dental technician

Manufacturer Details	Address	Certificate number(s)
Detax GmbH	Carl-Zeiss-Strass 4 , Ettlingen , 76275 Germany	

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. Tray, impression, dental

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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