



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Monocure 3D Pty Ltd

for approval to supply

Monocure 3D Pty Ltd - Dental material, modelling, polymer based

ARTG Identifier	398012
ARTG Start Date	19/10/2022
Product Category	Medical Device Included Class 1
GMDN	34811
GMDN Term	Dental material, modelling, polymer based
Intended Purpose	<p>This is a resin intended in combination with a 3D printer for temporary use in the mouth. It is autoclavable, biocompatible material engineered for the fabrication of surgical guides, temporary crowns, bridges and try-in dentures. Optimised for MSLA and DLP 3D printers, accurately realises glue channels, positioning windows, and drill holes allowing clinicians to effectively place implants accurately and with ease. Also, to reduce patient visits and obtain patient approval prior to manufacturing a full denture.</p> <p>This resin is available in a range of Vita Colour shades including A1, A2, A3, B1, B2, B3.</p>

Manufacturer Details	Address	Certificate number(s)
Monocure 3D Pty Ltd	Unit 16 / 364 Park Road Regents Park , NSW , 2143 Australia	

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 material, modelling, polymer based

Product Specific Conditions

No specific conditions have been recorded against this entry.