



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 383302 Kulzer Australia Pty Ltd - Dental acrylic resin

ARTG entry for Medical Device Included Class IIa
Sponsor Kulzer Australia Pty Ltd
Postal Address Unit 20 53 Lorraine St, PEAKHURST, NSW, 2210
Australia
ARTG Start Date 1/02/2022
Product Category Medical Device Class IIa
Status Active
Approval Area Medical Devices

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.

Manufacturers

Name	Address
Retec Kunststofftechnik GmbH	Industriestrasse 2 , Rosbach, 61191 Germany

Products

1 . Dental acrylic resin

Product Type	Single Device Product	Effective Date	1/02/2022
GMDN	63591 Dental acrylic resin		
Intended Purpose	To be used in dentistry for the for the production of veneers for dental prosthetics including; - Telescopic work - Model cast prosthetics - Implant structures - Cover dentures - Aesthetic try-ons - CAD/CAM bridges and bars - Laboratory manufactured temporary restorations		

Specific Conditions

No Specific Conditions included on Record

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