



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 383305 Kulzer Australia Pty Ltd - Denture base resin, cured

**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
Dentca Inc	357 Van Ness Way Suite 250 Torrance, CA, 90501 United States Of America

### Products

#### 1 . Denture base resin, cured

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	1/02/2022
<b>GMDN</b>	16730 Denture base resin, cured		
<b>Intended Purpose</b>	This is a light-curable resin that is intended to be used for fabrication and repair of full and partial removable dentures and base plates. The material is an alternative to traditional heat-curable and auto polymerizing resins. Fabrication of dental prosthetics with dima Print Denture Base requires a computer-aided design and manufacturing (CAD/CAM) system.		

### Specific Conditions

No Specific Conditions included on Record

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