



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

## Public Summary

**Summary for ARTG Entry:** 383571 Kulzer Australia Pty Ltd - Dental crown/bridge resin, temporary

**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** 7/02/2022  
**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 . Dental crown/bridge resin, temporary

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	7/02/2022
<b>GMDN</b>	45236 Dental crown/bridge resin, temporary		
<b>Intended Purpose</b>	This is a C&B temp is a light-curable polymerizable resin to fabricate, by additive manufacturing, temporary crowns or bridges. The fabricated temporary crowns or bridges are an alternative to preformed temporary crowns or bridges. The fabrication of temporary crowns or bridges with dima Print C&B temp requires digital models of crowns or bridges, a stereolithographic additive printer, and curing light equipment		

### Specific Conditions

No Specific Conditions included on Record

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