



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Kulzer Australia Pty Ltd**

for approval to supply

**Kulzer Australia Pty Ltd - Artificial teeth, resin**

<b>ARTG Identifier</b>	383352
<b>ARTG Start Date</b>	2/02/2022
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	38643
<b>GMDN Term</b>	Artificial teeth, resin
<b>Intended Purpose</b>	These are a Print Denture Teeth is a light-curable polymerizable resin to fabricate, by additive manufacturing, preformed denture Teeth to be used in a denture. The fabricated tooth is an alternative to preformed plastic tooth for denture. The fabrication of denture tooth with dima Print Denture Teeth requires digital denture tooth files instead of physical moulds, a stereolithographic additive printer, and curing light equipment

Manufacturer Details	Address	Certificate number(s)
Dentca Inc	357 Van Ness Way Suite 250 Torrance , CA , 9050 1 United States Of America	DV-2022-MC-01067-1

## ARTG Standard Conditions

The above Medical Device Included Class IIa 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. Artificial teeth, resin

## Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
PO Box 100, Woden ACT 2606 Australia  
Phone: 1800 020 653  
Email: [info@tga.gov.au](mailto:info@tga.gov.au)

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