



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 383352 Kulzer Australia Pty Ltd - Artificial teeth, 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 2/02/2022
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 . Artificial teeth, resin

Product Type	Single Device Product	Effective Date	2/02/2022
GMDN	38643 Artificial teeth, resin		
Intended Purpose	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		

Specific Conditions

No Specific Conditions included on Record

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