



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 112556 Kulzer Australia Pty Ltd- Dental material, denture base, polymer based

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 18/10/2004
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
Kulzer GmbH	Leipziger Strasse 2 , Hanau, 63450 Germany

Products

1 . Dental material, denture base, polymer based

Product Type	Single Device Product	Effective Date	18/10/2004
GMDN	16728 Dental material, denture base, polymer based		
Intended Purpose	denture base material		

Specific Conditions

No Specific Conditions included on Record

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