



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	112640	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	19/10/2004	
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	Schlatterstr 2 Wasserburg, Deutschland, 88142 Germany

Products

1 . Artificial teeth, resin

Product Type	Single Device Product	Effective Date	19/10/2004
GMDN	38643 Artificial teeth, resin		
Intended Purpose	acrylic teeth for use in prosthetic and prosthodontic dentistry		

Specific Conditions

No Specific Conditions included on Record

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