



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

## Public Summary

<b>Summary for ARTG Entry:</b>	112640	Kulzer Australia Pty Ltd- Artificial teeth, resin
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<b>ARTG entry for</b>	Medical Device Included Class IIa
<b>Sponsor</b>	Kulzer Australia Pty Ltd
<b>Postal Address</b>	Unit 20 53 Lorraine St, PEAKHURST, NSW, 2210 Australia
<b>ARTG Start Date</b>	19/10/2004
<b>Product Category</b>	Medical Device Class IIa
<b>Status</b>	Active
<b>Approval Area</b>	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

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

### Specific Conditions

No Specific Conditions included on Record

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