



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	296265	Kulzer Australia Pty Ltd - Adhesive, dental impression
ARTG entry for	Medical Device Included Class 1	
Sponsor	Kulzer Australia Pty Ltd	
Postal Address	Unit 20 53 Lorraine St, PEAKHURST, NSW, 2210 Australia	
ARTG Start Date	14/11/2017	
Product Category	Medical Device Class 1	
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 . Adhesive, dental impression			
Product Type	Single Device Product	Effective Date	14/11/2017
GMDN	16658 Adhesive, dental impression		
Intended Purpose	Adhesive used in dentistry for making impression materials stick to impression tray.		

Specific Conditions

No Specific Conditions included on Record

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