



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 292298 Kulzer Australia Pty Ltd - Dental impression tray material

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 1/08/2017
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 . Dental impression tray material

Product Type	Single Device Product	Effective Date	1/08/2017
GMDN	58106 Dental impression tray material		
Intended Purpose	dima Print Impression blue is a monomer mixture based on acrylic esters for manufacturing dental individual trays to be used in combination with cara Print 4.0 and HiLite Power.		

Specific Conditions

No Specific Conditions included on Record

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