



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 296270 Kulzer Australia Pty Ltd - Impression material, dental, <specify>

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 . Impression material, dental, <specify>

| | | | |
|-------------------------|--|-----------------------|------------|
| Product Type | Single Device Product | Effective Date | 14/11/2017 |
| GMDN | 16674 Impression material, dental, <specify> | | |
| Intended Purpose | Used in dentistry to take impressions inside the mouth, i.e to create a reverse or negative model of the teeth and/or tissues inside the mouth, for the purposes of denture, crown & bridge or other dental prosthetic fabrications. | | |

Specific Conditions

No Specific Conditions included on Record

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