



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

## Public Summary

**Summary for ARTG Entry:** 373804 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** 30/08/2021  
**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
dent a pharm Produktionsgesellschaft mbH	Schusterring 35 , Barmstedt, 25355 Germany

### Products

#### 1 . Dental impression tray material

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	30/08/2021
<b>GMDN</b>	58106 Dental impression tray material		
<b>Intended Purpose</b>	For use in dentistry to be used as a light-curing tray material in the form of prefabricated, baseplates to make rigid, custom impression trays and bite-blocks, as well as for other indications. Can be cured in all ultraviolet and Halogen light-curing units.		

### Specific Conditions

No Specific Conditions included on Record

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