



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

Product Type	Single Device Product	Effective Date	30/08/2021
GMDN	58106 Dental impression tray material		
Intended Purpose	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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