



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 196127 Kerr Australia Pty Ltd - Impression material, dental, compound

ARTG entry for Medical Device Included Class 1
Sponsor Kerr Australia Pty Ltd
Postal Address Unit 6, 12 Mars Road, Lane Cove West, NSW, 2066
Australia
ARTG Start Date 29/03/2012
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
Spofadental AS	Markova 238 Jicin, , CZ-506 46 Czech Republic

Products

1 . Impression material, dental, compound

Product Type	Single Device Product	Effective Date	29/03/2012
GMDN	34799 Impression material, dental, compound		
Intended Purpose	Impression Compound is used for full or partial dental impressions.		

Specific Conditions

No Specific Conditions included on Record

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