



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370370	Ozdent Pty Ltd - Sterilization packaging, single-use
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ARTG entry for	Medical Device Included Class 1
Sponsor	Ozdent Pty Ltd
Postal Address	PO Box 7806, BAULKHAM HILLS, NSW, 2153 Australia
ARTG Start Date	29/06/2021
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
Ozdent Pty Ltd	Unit 12 6 Gladstone Road CASTLE HILL, NSW, 2154 Australia

Products

1 . Sterilization packaging, single-use

Product Type	Single Device Product	Effective Date	29/06/2021
GMDN	13735 Sterilization packaging, single-use		
Intended Purpose	single use sterilisation packaging wrap provides a tortuous pathway to impede microbial migration.		

Specific Conditions

No Specific Conditions included on Record

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