



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

## Public Summary

<b>Summary for ARTG Entry:</b>	370370	Ozdent Pty Ltd - Sterilization packaging, single-use
<b>ARTG entry for</b>	Medical Device Included Class 1	
<b>Sponsor</b>	Ozdent Pty Ltd	
<b>Postal Address</b>	PO Box 7806, BAULKHAM HILLS, NSW, 2153 Australia	
<b>ARTG Start Date</b>	29/06/2021	
<b>Product Category</b>	Medical Device Class 1	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	29/06/2021
<b>GMDN</b>	13735 Sterilization packaging, single-use		
<b>Intended Purpose</b>	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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