



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

## Public Summary

**Summary for ARTG Entry:** 335980 Bird Healthcare Pty Ltd - Mandible-repositioning antisnoring orthosis

**ARTG entry for** Medical Device Included Class 1  
**Sponsor** Bird Healthcare Pty Ltd  
**Postal Address** 18 Corporate Boulevard, BAYSWATER, VIC, 3153  
Australia  
**ARTG Start Date** 7/05/2020  
**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
Bird Healthcare Pty Ltd	18 Corporate Boulevard BAYSWATER, VIC, 3153 Australia

### Products

#### 1 . Mandible-repositioning antisnoring orthosis

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	7/05/2020
<b>GMDN</b>	47526 Mandible-repositioning antisnoring orthosis		
<b>Intended Purpose</b>	The device is an intraoral device (mandibular repositioning) intended to treat snoring and sleep apnea. The device is worn during sleep in order to reduce the incidence of snoring and obstructive sleep apnea.		

### Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary