



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

## Public Summary

**Summary for ARTG Entry:** 333587 ResApp Health Ltd - Polysomnography device application software

**ARTG entry for** Medical Device Included Class 1  
**Sponsor** ResApp Health Ltd  
**Postal Address** Level 12 100 Creek Street, Brisbane, QLD, 4000  
Australia  
**ARTG Start Date** 7/04/2020  
**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
ResApp Health Ltd	Level 12 100 Creek Street Brisbane, QLD, 4000 Australia

### Products

#### 1 . Polysomnography device application software

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	7/04/2020
<b>GMDN</b>	42238 Polysomnography device application software		
<b>Intended Purpose</b>	The intended use of the SleepCheck application ("app") is as a screening device used to analyse an adult's breathing and snore sounds during sleep to assess their risk of obstructive sleep apnoea (OSA). The app is designed to be used by laypersons over the age of 18 for their own use in a non-clinical environment such as their own home. This test does not provide a diagnosis and is not intended as a substitute for a sleep study.		

### Specific Conditions

No Specific Conditions included on Record

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