



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 324285 ResApp Health Ltd - Respiratory sound analysis software

ARTG entry for Medical Device Included Class IIa
Sponsor ResApp Health Ltd
Postal Address Level 12 100 Creek Street, Brisbane, QLD, 4000
Australia
ARTG Start Date 1/10/2019
Product Category Medical Device Class IIa
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 . Respiratory sound analysis software

Product Type	Single Device Product	Effective Date	1/10/2019
GMDN	64033 Respiratory sound analysis software		
Intended Purpose	The ResAppDx-EU v2 is a mobile software application indicated for use as an aid in the diagnosis of a set of respiratory diseases in patients aged 29 days or older by a clinician.		

Specific Conditions

No Specific Conditions included on Record

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