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 ResApp Health Ltd
Address Level 12 100 Creek Street Brisbane, QLD, 4000 Australia

Products

1. Respiratory sound analysis software

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Effective Date</th>
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<tr>
<td>Single Device Product</td>
<td>1/10/2019</td>
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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