



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

**Public Summary**

**Summary for ARTG Entry:** 336703 AirPhysio Pty Ltd - Mechanical positive pressure airway secretion-clearing device

**ARTG entry for** Medical Device Included Class 1  
**Sponsor** AirPhysio Pty Ltd  
**Postal Address** 45 Grass Tree Cct, Bogangar, NSW, 2488  
 Australia  
**ARTG Start Date** 20/05/2020  
**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
AirPhysio Pty Ltd	Unit 1 43 Greenway Drive Tweed Heads, NSW, 2486 Australia

**Products**

**1 . Mechanical positive pressure airway secretion-clearing device**

Product Type	Single Device Product	Effective Date	20/05/2020
<b>GMDN</b>	43947 Mechanical positive pressure airway secretion-clearing device		
<b>Intended Purpose</b>	A hand-held, mechanical device designed to remove excessive mucus or sputum (phlegm) from the lungs and upper airway of a patient typically suffering from cystic fibrosis (CF), bronchitis, or bronchiectasis and/or to treat and prevent atelectasis. A positive expiratory pressure (PEP) is created when a patient exhales into the device, typically causing a high-density stainless steel ball to rapidly fluctuate up and down to create vibrations in the chest wall which loosens the mucus for expectoration and also assists in lung expansion. Also known as a Flutter, it is a single-patient device designed for use both in a medical facility and in the home. This is a reusable device.		

**Specific Conditions**

No Specific Conditions included on Record

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