



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
GMDN	43947 Mechanical positive pressure airway secretion-clearing device		
Intended Purpose	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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