

Australian Government

Department of Health Therapeutic Goods Administration

<u>Therapeutic Goods Act 1989</u> <u>Approval under section 42DF for use of restricted representations by</u> <u>AirPhysio Pty Ltd</u>

I, Elizabeth Butt, as a delegate of the Secretary to the Department of Health, on receipt of an application from AirPhysio Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representation described in paragraph (A), for use in advertising the product identified in paragraph (B) to consumers.

(A)

• The AirPhysio device is designed to help remove excessive mucus or sputum (phlegm) from the lungs and upper airway of a patient with respiratory conditions (the **Representation**).

The **Representation** will always be accompanied by the following statement, prominently displayed or communicated¹ adjacent or in close proximity to the **Representation**, whenever the **Representation** is used in an advertisement:

• If you suffer from a respiratory condition, we recommend discussing the suitability of the device with your healthcare professional (the Advisory Statement).

(B)

• AirPhysio Pty Ltd - Mechanical positive pressure airway secretion-clearing device (ARTG 376021)

Dated this 10th day of February 2022

Signed electronically

Elizabeth Butt Delegate of the Secretary to the Department of Health Advertising and Compliance Education and Policy Section Regulatory Compliance Branch



¹ As defined in the applicable version of the Therapeutic Goods Advertising Code, as amended from time to time.