

Department of Health and Aged Care

Therapeutic Goods Administration

<u>Therapeutic Goods Act 1989</u> <u>Approval under section 42DF for use of restricted representations by</u> Kan-Breathe Australia

I, Michael Shum, as a delegate of the Secretary to the Department of Health, on receipt of an application from Kan-Breathe Australia, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph (**A**), for use in advertising the products identified in paragraph (**B**) to consumers.

(A) Kan-Breathe device is designed to be used by patients with diagnosed respiratory conditions to help loosen mucus from the throat and airway (the **Representation**)

The **Representation** must 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, Kan-Breathe recommends you discuss the suitability of the device with your healthcare professional (the **Advisory Statement**).
- (B) Kan-Breathe Australia Mechanical positive pressure airway secretionclearing device (ARTG 391310)

Dated this 11th day of November 2022

Signed electronically

Michael Shum Delegate of the Secretary to the Department of Health Advertising and Compliance Education and Policy Section Regulatory Compliance Branch

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 $^{^{}m 1}$ As defined in the applicable version of the Therapeutic Goods Advertising Code, as amended from time to time.