



## Australian Government

### Department of Health, Disability and Ageing

#### Therapeutic Goods Administration

## BMedical Pty Ltd – Smart Peak Flow and Smart Asthma App - Peak flow meter, electronic (ARTG 314360)

### *Therapeutic Goods Act 1989*

#### Approval under section 42DF for use of restricted representations by BMedical Pty Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from BMedical Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph **(A)**, for use in advertisements for the product identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated<sup>1</sup> in the advertisement in which the restricted representations are used.

#### **(A)**

- What is a Peak Flow Meter?  
A peak flow meter is a handheld device that measures how air moves out of the lungs. Peak flow monitoring may be useful for some people with asthma, particularly those with moderate to severe asthma, frequent flare-ups, or difficulty perceiving symptoms.
- The Smart Peak Flow device connects to the Smart Asthma Companion App to record and monitor your peak flow readings.
- If you are using the Smart Peak Flow as part of your asthma management plan, it's important to have support from your GP or another healthcare professional. They can help you understand your results and decide what steps to take if you see changes in your Peak Flows.
- Your peak flow readings can be shared from the app with your asthma care team. This data may be used to make changes to your asthma management plan if required.
- Peak Flow Meters can be useful to monitor changes in your airways if you have Asthma. Discuss with your Asthma Care team if the daily use of a Peak flow meter should be in an Asthma Management Plan. Smart Peak Flow conveniently tracks and records your results over time into the Smart Asthma Companion App.
  - With Smart Peak Flow you can share your results from the app with the medical professionals helping manage your asthma.
- With the Smart Asthma Companion app, you can track peak flow changes over time, log your symptoms, and log inhaler puffer usage.

---

<sup>1</sup> ***prominently displayed or communicated***, in relation to a statement in an advertisement, means:

(a) either:

- (i) for a visual statement—easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or
- (ii) for a spoken statement—able to be clearly heard and understood; and

(b) repeated as often as necessary to be noticed by a viewer or listener

**(B)**

- *Smart Peak Flow and Smart Asthma App - Peak flow meter, electronic* (ARTG 314360).

**(C)**

- The asthma management plan given to you by your GP or care team should always be followed and will tell you what action to take when there are changes in your symptoms or peak flow readings.
- The Smart Peak Flow can be used as part of your asthma management plan. Consult with your asthma care team to determine if the Smart Peak Flow is suitable for you.
- If you experience symptoms such as chest tightness, shortness of breath, coughing or wheezing, seek immediate emergency medical advice.
- In Australia, peak flow monitoring is generally not recommended for children under 12 years of age.

Dated this 24<sup>th</sup> day of October 2025

*Signed electronically*

Rowena Love

Delegate of the Secretary to the Department of Health, Disability and Ageing

Education Policy and Guidance Section

Regulatory Compliance Branch