



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Advertising Approval: Aero Health Aust Pty Ltd – ‘Automatic-inflation electronic sphygmomanometer, portable, arm/wrist’ (ARTG 455925)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Aero Health Aust Pty Ltd

I, Michael Shum, as a delegate of the Secretary to the Department of Health and Aged Care, on receipt of an application from Aero Health Aust 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 communicated¹ in the advertisement in which the restricted representations are used (including on the label and packaging of the goods).

(A)

- ADVANCED PARR (Pulse Arrhythmia) Technology detects the existence of pulse arrhythmia, including atrial fibrillation (Afib), Atrial and / or Ventricular Premature Contractions (PC).
- Arrhythmia Detection (ARR) helps identify irregular heartbeats during routine blood pressure measurements.
- Atrial Fibrillation Detection (AFib) assists in identifying rapid and irregular heartbeats originating in the heart's upper chambers.
- Premature Contraction Detection (PC) identifies early heartbeats that disrupt the regular cardiac rhythm.
- Hypertension Risk Indicator provides a visual indication of assumed risk level (based on 1999 WHO International Society of Hypertension Guidelines for management of hypertension).
- Representations which refer to a hypertension risk indication feature

(B)

- Automatic-inflation electronic sphygmomanometer, portable, arm/wrist (ARTG 455925)

(C)

- The device is not intended to replace traditional methods of diagnosis.
- If an irregular heartbeat or atrial fibrillation is detected, consult a doctor.

¹ ***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

- If the user has symptoms of a heart attack, stroke, or other cardiovascular conditions, do not rely on the notification of the device and call emergency services immediately.
 - This product is not a substitute for professional attention from a healthcare practitioner.
- together, (the **Representations**).

Dated this 6th day of November 24

Signed electronically

Michael Shum

Delegate of the Secretary to the Department of Health and Aged Care

Advertising and Compliance Education and Policy Section

Regulatory Compliance Branch