Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by Withings SA

I, Elizabeth Butt, as a delegate of the Secretary to the Department of Health, on receipt of an application from Withings SA have approved under section 42DF of the *Therapeutic Goods Act 1989* (the **Act**) the restricted representations described in paragraph (**A**) below for use in consumer advertising of the product identified in paragraph (**B**):

(A)

(i) Representations to the effect that the Device:

- monitors blood pressure and heart rate plus records heart sounds which may lead to the detection of two major under-diagnosed heart diseases, atrial fibrillation, and the most prevalent forms of valvular heart disease, which frequently occur among hypertensive people
- may detect an abnormal heart sound that may be indicative of valvular heart disease
- may detect an abnormal heart sound which may be a sign of valvular heart disease, condition characterised by a defect of the heart valves that may require surgical intervention to avoid heart failure
- may detect atrial fibrillation (A fib) and abnormal heart sounds, the latter of which could be a sign of valvular heart disease. Both conditions are widely under-diagnosed heart diseases which frequently occur in hypertensive people

(ii) Representations to the effect that users can save and share data with their healthcare provider, which may assist with hypertension management and early diagnosis

both of which will always be accompanied by all of the following advisory statements, prominently displayed, or communicated[1] and to the effect of:

- the Device is not intended to replace traditional methods of diagnosis; and
- if abnormal heart sounds or atrial fibrillation are detected, consult a doctor; and
- the Device cannot detect a heart attack, stroke, or other cardiovascular conditions. If you experience chest pain, pressure, tightness, or what you think is a heart attack, do not rely on the notification of the Device and call emergency services immediately

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

(B) Product marketed as "BPM Core" under the following entry in the Australian Register of Therapeutic Goods (ARTG):

- "Emergo Asia Pacific Pty Ltd T/a Emergo Australia – Automatic-inflation electronic sphygmomanometer, portable, arm/wrist" (ARTG 346217) (**the Device**)

Dated this 21st Day of July 2021

Signed electronically

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