Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by J A Davey Pty Ltd

I, Leanne McCauley, Delegate of the Secretary to the Department of Health, on receipt of an application from J A Davey Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989* (the **Act**) the restricted representations described in paragraph (A) below for use in advertisements directed to consumers, for the products identified in paragraph (B):

A)

i. The device can detect an irregular pulse suggestive of Atrial Fibrillation (Afib). The device is not intended to diagnose Afib. A diagnosis of Afib can only be confirmed by Electrocardiogram (ECG). If the Afib symbol appears, consult your doctor.
ii. This device detects the possibility of Atrial Fibrillation, so you can consult your doctor for early diagnosis and treatment, which may prevent stroke or heart failure.
iii. Atrial fibrillation is an arrhythmia that can be asymptomatic and intermittent and can lead to stroke and heart failure.
iv. Hypertension is a risk factor for Atrial Fibrillation.
v. Early detection/diagnosis of Atrial Fibrillation enables a doctor to start appropriate treatment, which may prevent stroke or heart failure.
vi. Stating accurate and current age-related prevalence of Atrial Fibrillation; and of stating the prevalence of stroke and heart failure cases due to Atrial Fibrillation.

B)

Automatic-inflation electronic sphygmomanometer, non-portable (ARTG 137264)

Dated this 17th day September 2020

Signed electronically

Leanne McCauley
Delegate of the Secretary to the Department of Health
Advertising Education and Assurance Section
Regulatory Compliance Branch