Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by Medtronic Australasia Pty Ltd

I, Rowena Love, Delegate of the Secretary to the Department of Health, on receipt of an application from Medtronic Australasia Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989* (**the Act**) the restricted representations to the effect of those described in paragraph (A) below for use in advertisements directed to consumers, for the product identified in paragraph (B):

A)

i. atrial fibrillation is an arrhythmia that can be asymptomatic and intermittent and can lead to stroke;

ii. the device referred to in paragraph (B) is a reliable screening tool that can detect atrial fibrillation;

iii. early detection/diagnosis of atrial fibrillation enables a doctor to start appropriate treatment, which may prevent stroke;

iv. hypertension is a risk factor for atrial fibrillation;

v. of stating accurate and current age-related prevalence of atrial fibrillation; and

vi. of stating the prevalence of stroke cases due to atrial fibrillation

B) Automatic-inflation electronic sphygmomanometer, non-portable (ARTG 301566)

Dated this 6th day of June 2019

Signed electronically

Rowena Love
Delegate of the Secretary to the Department of Health
Advertising Compliance Unit
Regulatory Education and Compliance Branch