



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by

Silverline Medical Pty Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health and Aged Care, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph (A), for use in advertising the product identified in paragraph (B) to consumers.

- (A)** 1. Representations to the effect the device has PARR Pulse Arrhythmia technology that detects atrial fibrillation, premature contractions and non type-specific arrhythmias.
2. Representations which refer to 'hypertension', the 'management of hypertension' and 'hypertension risk', only as they are used in the 'Blood Pressure Monitoring table' which is based on the 1999 WHO – International Society of Hypertension Guidelines for the management of Hypertension.
3. Representations which refer to a 'hypertension risk indicator' feature.
4. Atrial fibrillation (AFib) is a heart condition that causes an irregular and often rapid heart rate. It is a type of arrhythmia, which means that the heart beats in an abnormal rhythm.
5. Premature contraction is a type of arrhythmia that can originate in your heart's upper (atria) or lower (ventricles) chambers.

together, (the Representations).

The Representations will be accompanied by the following statements, prominently displayed and communicated, to the effect of the following:

- The device is not intended to replace traditional methods of diagnosis.
- If arrhythmia (ARR), premature contraction (PC) or atrial fibrillation (AFib) is detected consult a doctor for potential diagnosis or treatment.

- If user has symptoms of heart attack, stroke or other cardiovascular conditions do not rely on the notification of the device and consult a doctor.

(B) Automatic-inflation electronic sphygmomanometer, portable, arm/wrist (ARTG 421685)

Dated this 22nd day of December 2023

Signed electronically,

Rowena Love

Delegate of the Secretary to the Department of Health and Aged Care
Advertising and Compliance Education and Policy Section
Regulatory Compliance Branch