



Australian Government

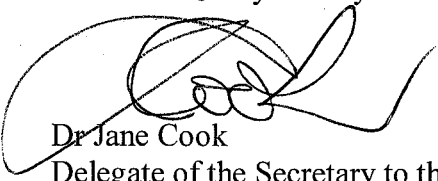
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989

I, Dr Jane Cook, Head, Office of Product Review, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health for the purposes of section 42DF(1) of the *Therapeutic Goods Act 1989*, give notice that the restricted representation described in paragraph (a) below has been approved for use in advertisements directed to consumers, for the products identified in paragraph (b) provided the conditions in paragraph (c) are met:

- (a) Representations to the effect that advertisements to consumers for the goods described in paragraph (b) may refer to: "irregular heartbeat" when used in the context of the phrase "irregular heartbeat detection/function/feature" (or words to that effect) to explain the "irregular heartbeat" icon;
- (b) Non invasive blood pressure monitors that are entered in the Australian Register of Therapeutic Goods as "Included Medical Devices" and have an "intended purpose" to the effect of being devices which are used to measure blood pressure, comprising a cuff to restrict blood flow and a monitor to measure pressure and which have a function to indicate an invalid blood pressure reading due to the presence of an irregular heartbeat; and
- (c) Subject to the condition that all consumers are prominently advised, such as in the product's Instructions for Use, that if the "irregular heartbeat" icon continues to appear, medical advice should be obtained.

Dated this 5 day of May 2014



Dr Jane Cook

Delegate of the Secretary to the Department of Health; and
Head
Office of Product Review