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 Roche Diagnostics Australia Pty Limited

I, Stephen Weber, 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 use of restricted representations described in paragraph (A) in advertising the products identified in paragraph (B) to consumers.

(A) 1. Representations to the effect that "anticoagulation medications, also known as blood thinners, are prescribed to avoid unwanted clots".

2. Representations to the effect that "the product is intended for the determination of prothrombin time or International Normalised Ratio (INR) as a general coagulation test to monitor the effect of Vitamin K antagonists, such as warfarin".

3. Representations to the effect that "the product is intended for the determination of prothrombin time (PT) in fresh capillary blood and is used as a general coagulation test to monitor Vitamin K Antagonist therapy".

4. Representations to the effect of "test your INR with a simple finger prick".

5. Representations to the effect that "results can be obtained in 1 min, and results can be tracked by built in graphic reports to help identify patterns and detect any drift in INR".
together, (the **Representations**).

The **Representations** must always be accompanied by the following statements, *prominently displayed or communicated*[1] adjacent or in close proximity to the **Representations**, whenever the **Representations** are used in an advertisement:

- Discuss the suitability of this product with your doctor.
- The product is intended for use by properly selected and appropriately trained people. Your pharmacist/specialist supplier can provide you the

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

training and/or put you in touch with associations or institutions offering training in coagulation self-monitoring.

- Self-monitoring supplements your doctor's care; it is not a substitute for it.
- Self-monitoring of oral anticoagulation therapy using coagulation values determined with the CoaguChek INRange system may only be undertaken after consultation with your doctor and comprehensive instruction by a qualified healthcare professional.

together, (the **Advisory Statements**).

(B) 1. General coagulation IVDs (CoaguChek XS PT Test PST) - ARTG 198119
2. Home-use/point-of-care coagulation analyser IVD, battery-powered (CoaguChek INRange) – ARTG 282998
3. Lancet tip (CoaguChek Softclix Lancet) – ARTG 296200

Dated this 11th day of December 2023

Signed electronically,

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