



**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**  
**Australasian Medical & Scientific Ltd**

I, Michael Shum, 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 products identified in paragraph (B) to consumers.

- (A) 1. Representations referring to “diabetes” in the context of the Applicant’s and manufacturer’s trading names.
2. Representations to the effect of “This product is a continuous glucose monitoring system indicated for the management of (type 1, type 2, gestational) diabetes in people aged 2 years and older where self-monitoring of blood glucose (SMBG) is indicated”.
3. Representations to the effect of “Anyone 2 years and older living with (type 1, type 2, gestational) diabetes may benefit from continuous glucose monitoring/CGM where self-monitoring of blood glucose (SMBG) is indicated”.
4. “for people living with diabetes” this representation will only be used in advertisements that include the representation “this product is indicated for persons with diabetes mellitus age 2 years and older where self-monitoring of blood glucose (SMBG) is indicated”.
5. “Integrates with diabetes management applications”.
6. “Manage your diabetes with ZERO fingerpricks and no calibrations, even for treatment decisions” (the Fingerprick Statement).
7. “If your glucose alerts and readings from the G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions” (the Advisory Statement), with the Advisory Statement prominently displayed or communicated adjacent, or in close proximity to the Fingerprick Statement, whenever the Fingerprick Statement is used in consumer advertising.
- together, (the **Representations**).

**(B)** Glucose monitoring system, in vivo (ARTG 169241)  
G6 Sensor Kit - Subcutaneous glucose sensor (ARTG 330535)  
Self-care monitoring web-based application software (ARTG 285956)  
together, (the **Device System**).

Dated this 29th day of September 2023

*Signed electronically*

**Michael Shum**

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