



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, on receipt of an application from Australasian Medical & Scientific Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph (A), in advertisements for the products identified in paragraph (B) to consumers, when the statements identified in paragraph (C) are prominently displayed or communicated¹ (including on the label and packaging of the goods).

(A)

1. Representations referring to “diabetes” in the context of the Applicant's and legal manufacturer’s trading name.
2. Representations to the effect of “This product is a continuous glucose monitoring system indicated for the management of diabetes in people age 2 years and older where self-monitoring of blood glucose (SMBG) is indicated”
3. Representations to the effect of “Anyone over 2 years of age living with type 1, type 2, or gestational diabetes where self-monitoring of blood glucose (SMBG) is indicated may benefit from continuous glucose monitoring/CGM”
4. For people aged 2 years or older living with type 1, type 2 and gestational diabetes where self-monitoring of blood glucose (SMBG) is indicated
5. For people living with type 1 diabetes
6. For people living with type 2 diabetes
7. For people living with diabetes
8. Integrates with diabetes management applications
9. “Manage your diabetes with ZERO finger-pricks” (the Finger-prick Statement).
10. “If your glucose alerts and readings from the device do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions” (the Advisory Statement). The Advisory Statement must be prominently displayed or communicated whenever the Finger-prick Statement is used in consumer advertising.

(B)

- G7 Glucose Sensing Subsystem (GSS) - Invasive interstitial-fluid glucose monitoring system (ARTG 453426);
- Glucose monitoring system, in vivo (ARTG 169241);

¹ ***prominently displayed or communicated***, in relation to a statement in an advertisement, means:

(a) either:

- (i) for a visual statement—easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or
- (ii) for a spoken statement—able to be clearly heard and understood; and

(b) repeated as often as necessary to be noticed by a viewer or listener.

- Self-care monitoring web-based application software (ARTG 285956).

(C)

- Representations 5, 6 and 7 used alone or together must 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*” prominently displayed or communicated.

Dated this 13th day of September 2024

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