



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

**Advertising Approval: Australasian Medical & Scientific Ltd - Dexcom - Glucose monitoring system, in vivo (ARTG 169241); Dexcom - Self-care monitoring web-based application software (ARTG 285956) Dexcom Continuous Glucose Monitoring System (CGM System) - Subcutaneous glucose sensor (ARTG 472165)**

***Therapeutic Goods Act 1989***

**Approval under section 42DF for use of restricted representations by Australasian Medical & Scientific Ltd**

I, Rowena Love, 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), for use in advertisements for the products identified in paragraph (B), when the statements identified in paragraph 7.a are prominently displayed or communicated<sup>1</sup> in the advertisement in which the restricted representations are used (including on the label and packaging of the goods), subject to the condition identified in paragraph (C).

**(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. Representations to the effect of “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. Representations to the effect of “For people living with type 1 diabetes”.
6. Representations to the effect of “For people living with type 2 diabetes”.
7. Representations to the effect of “For people living with diabetes”

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<sup>1</sup> ***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

- a. Representations 5, 6, or 7 used singly or together 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"
8. Representations to the effect of "Integrates with Dexcom 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)**

- Dexcom - Glucose monitoring system, in vivo (ARTG 169241)
- Dexcom - Self-care monitoring web-based application software (ARTG 285956)
- Dexcom Continuous Glucose Monitoring System (CGM System) - Subcutaneous glucose sensor (ARTG 472165)

**(C)**

- Advertisements in which any one of the approved representations is used must comply with the Therapeutic Goods Advertising Code (the Code).

Dated this 21<sup>st</sup> day of January 2025.

*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