



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 - Subcutaneous glucose sensor (ARTG 462866)**

**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), for use in advertisements for the product identified in paragraph (B), when the statement identified in paragraph 7.a is 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 conditions 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 aged 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. Representation to the effect of "Manage your diabetes with zero finger-pricks" (the **Finger-prick Statement**).
10. Representation to the effect of "*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 whenever the Finger-prick Statement is used in consumer advertising.

together, (the **Representations**).

**(B)**

- Dexcom - Glucose monitoring system, in vivo (ARTG 169241)
- Dexcom - Subcutaneous glucose sensor (ARTG 462866)
- Dexcom - Self-care monitoring web-based application software (ARTG 285956)

together, (the **Device System**).

**(C)**

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

Dated this 20th day of December 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