



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

**Medtronic Australasia Pty Ltd – Guardian 4 sensor - Subcutaneous glucose sensor (ARTG 475489) Guardian Transmitter - Invasive interstitial-fluid glucose monitoring system (ARTG 374791)**

***Therapeutic Goods Act 1989***

**Approval under section 42DF for use of restricted representations by Medtronic Australasia Pty Ltd**

I, Rowena Love, as a delegate of the Secretary to the Department of Health and Aged Care, on receipt of an application from Medtronic Australasia Pty 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).

**(A)**

- Representations referring to “diabetes” in the context of the name “Medtronic Diabetes”
- The Guardian 4 sensor is intended for use with a Guardian 4 transmitter to monitor glucose levels in persons with diabetes where self-monitoring of blood glucose (SMBG) is indicated.
- The sensor is designed to replace fingerstick blood glucose (BG) readings for diabetes treatment decisions.
- The sensor is intended for insertion into persons with diabetes ages 7 years and older
- ‘Diabetes management with no calibrations’ (the **Calibration statement**)
  - Whenever the ‘Calibration statement’ is used in consumer advertising an advisory statement to the effect “*if sensor glucose (SG) values do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions. Refer to System User Guide*” will be prominently displayed or communicated<sup>1</sup> adjacent or in close proximity to the Calibration statement

**(B)**

- Guardian 4 sensor - Subcutaneous glucose sensor (ARTG 475489)
- Guardian Transmitter - Invasive interstitial-fluid glucose monitoring system (ARTG 374791)

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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.

Dated this 29<sup>th</sup> day of April 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