



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

## Advertising Approval: Medtronic Australasia Pty Ltd - Simplera Sensor - Subcutaneous glucose sensor (ARTG 475490); Simplera Mobile App - Diabetes patient management software (ARTG 461685)

### ***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, Disability and Ageing, 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 Device System identified in paragraph **(B)** subject to the condition identified in paragraph **(C)**.

#### **(A)**

1. Representations referring to “diabetes” in the context of the name “Medtronic Diabetes”.
2. Simplera sensor is a single-patient, single-use component of the Medtronic personal continuous glucose monitoring (CGM) system. Simplera sensor is indicated for the management of diabetes in persons ages 2 years and older where self-monitoring of blood glucose (SMBG) is indicated.
3. Simplera sensor is designed to replace fingerstick blood glucose (BG) readings for diabetes treatment decisions. For the first 24 hours, children between the ages of 2 to 6 are required to check BG values prior to making therapy decisions.
4. The Simplera sensor benefits users by eliminating the discomfort associated with fingerstick glucose measurements used for calibration or confirmation of the information provided by the CGM system.
5. Representation to the effect of: “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’” (the **Advisory Statement**).
  - a. With the Advisory Statement being prominently displayed or communicated<sup>1</sup> whenever the representations outlined in paragraphs 3 or 4 are used in consumer advertising.

together, (the **Approved Representations**)

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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.

**(B)**

- Simplera Sensor - Subcutaneous glucose sensor (ARTG 475490)
- Simplera Mobile App - Diabetes patient management software (ARTG 461685).

Together, (the Device System)

**(C)**

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

Dated this 14<sup>th</sup> day of May 25

*Signed electronically*

Rowena Love

Delegate of the Secretary to the Department of Health, Disability and Ageing  
Education Policy and Guidance Section  
Regulatory Compliance Branch