



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Advertising Approval: Medtronics Australasia Pty Ltd – Simplera Sensor- Subcutaneous glucose sensor (ARTG 447610) and Simplera Mobile App (ARTG 461685)

Therapeutic Goods Act 1989

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

I, Michael Shum, 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 product identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated¹ 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 **(D)**.

(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.

together, (the **Approved Representations**).

(B)

- Simplera Sensor - Subcutaneous glucose sensor (ARTG 447610)
- Simplera Mobile App (ARTG 461685)

(C)

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

- 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**).
 - The Advisory Statement must be prominently displayed or communicated¹ whenever the representations outlined in paragraphs 3 or 4 are used in consumer advertising.

(D)

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

Dated this 6th day of January 2025

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