



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medtronic Australasia Pty Ltd – Simplera Sync sensor - Subcutaneous glucose sensor (ARTG 471365)

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 use of restricted representations that refer, either expressly or by necessary implication, to diabetes, as 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)

- Simplera Sync sensor with Bluetooth wireless technology is a component of a compatible Medtronic insulin pump system.
- Representations referring to “diabetes” in the context of the name “Medtronic Diabetes”.
- Simplera Sync sensor is a single-patient, single-use component of a personal continuous glucose monitoring (CGM) system.
- Simplera Sync sensor is intended to communicate via Bluetooth Low Energy (BLE) with a compatible Medtronic insulin pump system to provide glucose information for diabetes management.
- Simplera Sync sensor is indicated for the management of diabetes in persons ages 7 years and older.
- Simplera Sync sensor does not require calibration.

(B)

- Simplera Sync sensor - Subcutaneous glucose sensor (ARTG 471365)

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

(C)

- If sensor glucose (SG) values do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decision.

(D)

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

Dated this 27th day of February 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