



Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by
Australasian Medical & Scientific Ltd

I, Leanne McCauley, as a delegate of the Secretary to the Department of Health, on receipt of an application from Australasian Medical & Scientific Ltd have approved under section 42DF of the *Therapeutic Goods Act 1989* (the **Act**) the restricted representations described in paragraph **(A)** for use in advertisements directed to consumers for the products identified in paragraph **(B)** and the restricted representations described in paragraph **(C)** below for use in advertisements directed to consumers for the product identified in paragraph **(D)**:

(A)

- Representations referring to “diabetes” in the context of the name “*AMSL Diabetes*”
- “*This product is a continuous glucose monitoring system indicated for the management of type 1 diabetes in persons aged 2 years and older*”
- “*For people living with type 1 diabetes*”
- “*Anyone over two years of age living with type 1 diabetes may benefit from continuous glucose monitoring/CGM*”

(B)

- AA-Med Pty Ltd – G6 Sensor Kit – subcutaneous glucose sensor (ARTG 330535).
- AA-Med Pty Ltd – G5/G4 PLATINUM Sensor Kit – subcutaneous glucose sensor (ARTG 318476).

(C)

- “*Manage your diabetes with ZERO fingerpricks and no calibrations, even for treatment decisions*” (the **Fingerprick Statement**).
- “*If your glucose alerts and readings from the G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions*” (the **Advisory Statement**), with the Advisory Statement prominently displayed or communicated adjacent, or in close proximity to the Fingerprick Statement, whenever the Fingerprick Statement is used in consumer advertising.

(D)

- AA-Med Pty Ltd – G6 Sensor Kit – subcutaneous glucose sensor (ARTG 330535).

Dated this 9th day of March 2021

Signed electronically

Leanne McCauley
Delegate of the Secretary to the Department of Health
Advertising and Compliance Education and Policy Section
Regulatory Compliance Branch