

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Advertising Approval: SiSU Wellness Pty Ltd – SiSU Health Station – Patient monitor module, multifunction (ARTG 317543)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by SiSU Wellness Pty Ltd

I, Michael Shum, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from SiSU Wellness Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representation described in paragraph **(A)**, for use in advertisements for the product identified in paragraph **(B)**, and under section 42DF(3) of the Act, I have decided to impose a condition on the approval of the use of the restricted representation, which is outlined in paragraph **(C)**.

(A)

· 'Diabetes risk'

(B)

· SiSU Health Station – Patient monitor module, multifunction (ARTG 317543)

(C)

The restricted representation 'diabetes risk' must only be used in advertising about the 'SiSU Health Station – Patient monitor module, multifunction (ARTG 317543)' when referring to an established health questionnaire about the risk of developing type 2 diabetes that is relevant to the Australian population, such as 'The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)'.

Dated 1 August 2025

Signed electronically

Michael Shum

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

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