



Australian Government

Department of Health, Disability and Ageing Therapeutic Goods Administration

Air Liquide Healthcare Pty Ltd – Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Continuous glucose monitoring system - Invasive interstitial-fluid glucose monitoring system (ARTG 498525) and Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Subcutaneous glucose sensor (ARTG 498526)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Air Liquide Healthcare 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 Air Liquide Healthcare 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 products 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.

(A)

1. Representations referring to “diabetes” in the context of the Applicant’s business name “Air Liquide Healthcare Diabetes”; and

Representations to the effect:

2. For the continuous monitoring of interstitial fluid glucose levels in patients 3 years and older with type 1 or type 2 diabetes.
3. For the continuous monitoring of glucose levels in patients 3 years and older with type 1 or type 2 diabetes.
4. For people living with type 1 diabetes.
5. For people living with type 2 diabetes.
6. For people living with diabetes (only for use in combination with representation 2).

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

(B)

- Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Continuous Glucose Monitoring System - Invasive interstitial-fluid glucose monitoring system (ARTG 498525)
- Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Subcutaneous glucose sensor (ARTG 498526)

(C)

- Do a blood glucose test with a fingerstick and your blood glucose meter if you think your glucose readings are not correct or do not match how you feel. Do not ignore symptoms that may be due to low or high glucose. Seek medical attention when appropriate.

Dated this 6th day of November 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