



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Swallowing Technologies Ltd – Biofeedback system (ARTG 479030)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Swallowing Technologies Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from Swallowing Technologies Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph **(A)**, presented together and with equal prominence, for use in advertisements for the product identified in paragraph **(B)**.

(A)

Representations to the effect that:

- Dysphagia is a recognised swallowing disorder that may cause symptoms including coughing during swallowing, choking, or the sensation of food becoming stuck in the throat.
- Individuals experiencing symptoms of dysphagia should seek assessment from an appropriately qualified healthcare professional.
- BiSSkApp is intended to visualise muscle activity and may be used by qualified healthcare professionals as part of dysphagia rehabilitation and recovery programs.
- Skill-based swallowing rehabilitation and biofeedback-supported interventions may improve swallowing function, swallowing-related quality of life, and rehabilitation outcomes in appropriately selected dysphagia populations.
- BiSSkApp is used under professional supervision and is not intended for self-diagnosis or self-treatment of dysphagia.

(B)

Biofeedback system (ARTG 479030).

Dated this 7th day of October 26

Signed electronically

Rowena Love

Delegate of the Secretary to the Department of Health, Disability and Ageing

Education Policy and Guidance Section

Regulatory Compliance Branch