



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by

Molnlycke Health Care Pty Ltd

I, Michael Shum, as a delegate of the Secretary to the Department of Health and Aged Care, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph (A), for use in advertising the product identified in paragraph (B) to consumers.

- (A)** 1. *Mepilex Border Flex Lite is designed for wounds with none to moderate levels of fluid.*
2. *Mepilex Border Flex Lite is designed for wounds such as leg and foot ulcers, pressure injuries, surgical wounds and traumatic wounds.*
together, (the **Representations**).

The Representations will be accompanied by the following advisory statements:

- *Mepilex Border Flex Lite can be used by lay persons under supervision of Healthcare Professionals*
- *If you are concerned about your wound, please contact your Healthcare Professional.*

- (B)** Dressing, wound-nonadherent, absorbent (ARTG 356900).

Dated this 16 day of June 2023

Signed electronically

Michael Shum

Delegate of the Secretary to the Department of Health and Aged Care
Advertising and Compliance Education and Policy Section
Regulatory Compliance Branch