



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 is designed for wounds that have moderate to high amounts of fluid.*
2. *Mepilex Border Flex is designed for wounds such as pressure injuries, leg and foot ulcers, traumatic wounds, dry/necrotic wounds in combination with gels and surgical wounds.*
together, (the **Representations**).

The Representations will be accompanied by the following advisory statements:

- *Mepilex Border Flex 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 216111).

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