



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Molnlycke Health Care Pty Ltd – Mepore, Mepore Film & Pad and Mepore Pro - Adhesive bandage (ARTG 205811)

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, on receipt of an application from Molnlycke Health Care 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 product 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 (including on the label and packaging of the goods).

(A)

- Mepore is intended for use on low to moderately fluid wounds, such as surgical wounds, cuts and abrasions.
- Mepore Film & Pad is intended for use on low to moderately fluid wounds, such as surgical wounds, cuts and abrasions.
- Mepore Pro is intended for use on low to moderately fluid wounds, such as surgical wounds, cuts and abrasions.

(B)

- ARTG 205811 - Adhesive bandage

(C)

- [One or more of the following product names: Mepore / Mepore Film & Pad / Mepore Pro] can be used by lay persons under supervision of Healthcare Professionals.
- If you are concerned about your wound, please contact your Healthcare Professional together, (the **Representations**).

Dated this 23rd day of October 24

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

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