

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, Rowena Love, 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 communicated in advertisements in which the restricted representations are used.

(A)

- Mepilex Ag is intended to be used on infected wounds or wounds at risk of infection with low to moderate amounts of wound fluid, such as:
 - leg and foot ulcers
 - pressure injuries
 - partial-thickness burns

(B)

Mepilex Ag - Wound-nonadherent dressing, absorbent, antimicrobial (ARTG 154420)

(C)

- Mepilex Transfer Ag should be used under the supervision of a qualified Healthcare Professional.
- If you are concerned about your wound, please contact your Healthcare Professional together, (the **Representations**).

Dated this 16th day of September 24 *Signed electronically,*

Rowena Love

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

PO Box 100 Woden ACT 2606 ABN 40 939 406 804 Phone: 1800 020 653 or 02 6289 4124 Fax: 02 6203 1605

Email: info@tga.gov.au https://www.tga.gov.au

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