



**Australian Government**  

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**Department of Health and Aged Care**  
Therapeutic Goods Administration

## **Advertising Approval: Molnlycke Health Care Pty Ltd – Mepitel - Dressing, wound-nonadherent, permeable (ARTG 177725)**

### ***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)**(1) and (2) when either (A)(1) or (A)(2) are used in their entirety, for use in advertisements for the product identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated<sup>1</sup> in the advertisement in which the restricted representations are used (including on the label and packaging of the goods).

#### **(A)**

1. Mepitel is a soft silicone wound contact layer designed for the management of wounds that have moderate to high amounts of wound fluid including:
  - § skin tears
  - § skin abrasions
  - § sutured wounds
  - § partial-thickness burns
  - § partial and full thickness grafts
  - § diabetic foot ulcers
  - § leg ulcers

Mepitel is applied directly to the wound with a secondary absorbent dressing then applied on top and can then be secured with a tubular bandage (ie: Tubifast or equivalent).

2. Mepitel (in conjunction with a secondary dressing) can be used as a protective layer on wounds with none to low amounts of fluid including: blisters, fragile skin and exposed fragile tissues.

#### **(B)**

- Mepitel - Dressing, wound-nonadherent, permeable (ARTG 177725)

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<sup>1</sup> ***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

**(C)**

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

Dated this 5th day of November 2024

*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