



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Molnlycke Health Care Pty Ltd – Mepitel One - Dressing, wound-nonadherent, permeable (ARTG 319329)

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 representation 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 representation is used (including on the label and packaging of the goods), subject to the condition identified in paragraph **(D)**.

(A)

- Mepitel One is a wound contact layer designed to be used for wounds of low to mid-levels of wound fluid such as: skin tears, skin abrasions, surgical incisions, partial thickness burns, traumatic wounds, partial and full thickness grafts, irradiated skin, leg and foot ulcers. Mepitel One should be secured with an outer absorbent dressing in order to fixate. It can also be used as a protective layer on blisters and on areas with fragile skin
in its entirety (the Approved Representation).

(B)

- Mepitel One - Dressing, wound-nonadherent, permeable (ARTG 319329)

(C)

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

(D)

- Advertisements in which the Approved Representation is used must comply with the Therapeutic Goods Advertising Code (the Code).

Dated this 4th day of February 2025.

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

Rowena Love

Delegate of the Secretary to the Department of Health and Aged Care

Advertising and Compliance Education and Policy Section

Regulatory Compliance Branch