



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, 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 use of restricted representations described in paragraph **(A)**, in advertisements for the product identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated¹ when either one or both of the restricted representations in paragraph **(A)** are used.

(A)

- Mepilex Border Sacrum/Mepilex Border Heel are self-adherent soft silicone dressings designed to be a part of prevention strategies of skin damage such as pressure injuries and to reduce post-operative blistering.
- Mepilex Border Sacrum/Mepilex Border Heel are also designed for wounds that have medium to high levels of fluid and can be used on wounds such as pressure injuries, leg ulcers, foot ulcers, traumatic wounds (e.g, skin tears) and surgical wounds.

(B)

- Dressing, wound-nonadherent, absorbent (ARTG 289489)

(C)

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

¹ As defined in the applicable version of the Therapeutic Goods Advertising Code, as amended from time to time.

Dated this 22nd day of January 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