



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, 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 representation described in paragraph (A), for use in advertising the product identified in paragraph (B), when the statements identified in paragraph (C) are prominently displayed or communicated¹ in such advertisements where the restricted representation in paragraph (A) is used. Additionally, I have also approved under section 42DF of the *Therapeutic Goods Act 1989*, the use of the restricted representations in paragraph (D), in advertisements about the product identified in paragraph (E), when the statements identified in paragraph (F) are prominently displayed or communicated¹ in such advertisements where either one or both of the restricted representations in paragraph (D) are used.

(A)

- Granudacyn solution is designed for the cleansing and irrigation of all acute and hard-to-heal wounds of any depth (such as diabetic foot ulcers, leg ulcers and pressure injuries), surgical wounds and partial thickness burns.

(B)

- Non-sterile wound irrigation solution, antimicrobial (ARTG 327412).

(C)

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

(D)

- Granudacyn wound gel is designed for cleansing and moistening acute and hard-to-heal wounds, including infected wounds and partial thickness burns.
- Granudacyn Wound gel is designed for cleansing and moistening acute and hard-to-heal wounds.

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

(E)

- Non-sterile wound irrigation solution, antimicrobial (ARTG 327413)

(F)

- Granudacyn Gel can be used by lay persons under supervision of Healthcare Professionals.
- If you are concerned about your wound, please contact your Healthcare Professional.
- Advisory statement to the effect of: *"Please ensure to clean the wound and surrounding area with Granudacyn Wound Irrigation solution and dab dry. Apply Granudacyn Wound gel to the affected areas and cover with a suitable secondary dressing."*

Dated this 27th day of March 2024

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