



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 the restricted representations in paragraph (A), in advertisements about the products identified in paragraph (B), when the statements identified in paragraph (C) are prominently displayed or communicated¹ in such advertisements where either one or both of the restricted representations in paragraph (A) are 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 products 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)

- The Avance Solo Negative Pressure Wound Therapy (NPWT) System is indicated for patients who would benefit from wound management via the application of negative pressure to promote wound healing through the removal of wound fluid.
- The Avance Solo NPWT System is indicated for removal of low to moderate amounts of wound fluid from hard to heal wounds including: leg and foot ulcers and pressure injuries; as well as acute wounds including: surgically closed wounds, skin grafts and skin flaps.

(B)

- Negative-pressure wound therapy system canister (ARTG 375426)
- Negative-pressure wound therapy system dressing set (ARTG 375552)
- Negative-pressure wound therapy system foam dressing (ARTG 375412)
- Avance Solo NPWT System - Negative-pressure wound therapy system, battery-powered, single-use (ARTG 375497)
- Avance Solo NPWT System - Negative-pressure wound therapy system, battery-powered, single-use (ARTG 375853)
- Negative-pressure wound therapy system, battery-powered, single-use (ARTG 428537)
together, (the Avance Solo NPWT System).

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

(C)

- The Avance Solo NPWT System is intended to be prescribed and used by healthcare professionals for therapy on adult patients in healthcare facilities and home care settings.
- Avance Solo NPWT System can be used by lay persons with training and ongoing supervision given by Healthcare Professionals.
- Avance Solo NPWT System dressings should only be applied and changed by your Healthcare Professional.
- If you are concerned about your wound, please contact your Healthcare Professional.

(D)

- The Avance Solo Adapt Negative Pressure Wound Therapy (NPWT) System is indicated for patients who would benefit from wound management via the application of negative pressure to promote wound healing through the removal of wound fluid.
- The Avance Solo Adapt NPWT System is indicated for removal of low to moderate amounts of wound fluid from Pressure Ulcers.

(E)

- Avance Solo Adapt NPWT System - Negative-pressure wound therapy system, battery-powered, single-use (ARTG 375498)
- Avance Solo Adapt NPWT System Sets - Negative-pressure wound therapy system dressing set (ARTG 375561)
- Negative-pressure wound therapy system drape (ARTG 375413) together, (the Avance Solo Adapt NPWT System).

(F)

- The Avance Solo Adapt NPWT System is intended to be prescribed and used by healthcare professionals for therapy on adult patients in healthcare facilities and home care settings.
- Avance Solo Adapt NPWT System can be used by lay persons with training and ongoing supervision given by Healthcare Professionals.
- Avance Solo Adapt NPWT System dressings should only be applied and changed by your Healthcare Professional.
- If you are concerned about your wound, please contact your Healthcare Professional.

Dated this 1st day of February 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