



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Smith & Nephew Pty Ltd – PICO 7 - Negative-pressure wound therapy system, battery-powered, single-use (ARTG 185785)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Smith & Nephew 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 Smith & Nephew Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations 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 representations are used (including on the label and packaging of the goods), subject to the conditions identified in paragraph (D).

(A)

- Adequate education about surgical site infections is important to ensure mothers to be are aware of any potential risk factors associated with caesarean delivery, such as diabetes.
 - This representation will always be accompanied by words the effect of:
 - § The PICO 7 System can help reduce the risk of surgical site / incision infections after caesarean section
 - This representation will always be accompanied by words to the effect of:
 - § Speak to your doctor about interventions to help prevent surgical site complications

together, (the **Representations**).

(B)

- PICO 7 - Negative-pressure wound therapy system, battery-powered, single-use (ARTG 185785)

(C)

- PICO7 is to be used under the direction of Healthcare Professional only.
- The device can be used in homecare setting under the training and supervision from Healthcare Professional.
- PICO7 dressings should only be applied and changed by your Healthcare Professional.

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

(D)

- Advertisements in which any one of the Approved Representations is used must comply with the Therapeutic Goods Advertising Code (the Code).

Dated this 27th day of February 25

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