

Australian Government

Department of Health and Aged Care Therapeutic Goods Administration

<u>Therapeutic Goods Act 1989</u> <u>Approval under section 42DF for use of restricted representations by</u> Becton Dickinson Ptv Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health and Aged Care, 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) to consumers.

- (A) Representation to the effect: 'The PleurX drainage system is used for pleural effusions, which is fluid build-up around lungs, which causes breathing difficulty', when the statement 'You should have been trained by a healthcare professional in the correct way to use the items in the kit' is displayed in close proximity to the representation and when the advertisements in which the representation is used targets the relevant patient population group and is not generally available to consumers outside the patient population.
- **(B)** Pleural/peritoneal cavity drain-insertion set (ARTG 322783).

Dated this 20th day of June 2023

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