



Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Advertising Approval: Medtronic Australasia Pty Ltd – InPen - Electronic insulin pen (ARTG 454267); InPen App - Diabetes patient management software (ARTG 485045)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Medtronic Australasia Pty Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from Medtronic Australasia 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 products (identified as the Device System) in paragraph (B)

(A)

1. Representations referring to “diabetes” in the context of the name “Medtronic Diabetes” and representations to the effect of the following:
2. The InPen System can help with the management of diabetes.
3. InPen App - helps with calculating bolus doses. Take the right insulin dose at the right time.
4. Set alerts and reminders so you don't forget to take your insulin.
5. View and share diabetes therapy reports with your healthcare provider.
6. The InPen System (InPen App): includes a digital diabetes logbook for recording blood sugar readings, which can help with the management of diabetes. Log all insulin from all sources into the logbook as too much insulin can cause hypoglycemia.
7. InPen System (InPen App): your diabetes data in one place.
8. The InPen is compatible with Lilly Humalog, Novo Nordisk NovoRapid, Novo Nordisk Fiasp insulin cartridges
9. For Single Patient Use by people with diabetes for the self-injection of a desired dose of insulin.

An advertisement in which any of the representations in 1 to 9 is used, must contain a statement, prominently displayed or communicated¹ to the effect:

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

- A healthcare professional should assist in programming of the device prior to use, based on various patient-specific criteria and targets.

(B)

- InPen - Electronic insulin pen (ARTG 454267)
- InPen App - Diabetes patient management software (ARTG 485045)

together, the **Device System**

To avoid doubt, a reference in an advertisement that is made in accordance with this approval notice, relating to therapeutic goods containing a substance included in Schedule 3, 4 or 8 to the current Poisons Standard is by virtue of this approval notice also authorised by the Australian Government Department of Health, Disability and Ageing for the purposes of subsections 42DL(10) and 42DLB(7) of the Act

Dated this 12th day of June 2025

Signed electronically

Rowena Love

Delegate of the Secretary to the Department of Health, Disability and Ageing

Education Policy and Guidance Section

Regulatory Compliance Branch