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 Medtronic Australasia 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 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 advertising the product identified in paragraph (**B**) to consumers.

(A) 1. For Single patient use by people with diabetes for the self-injection of a desired dose of insulin

2. Take the right insulin dose at the right time
3. Log all insulin from all sources into the logbook as too much insulin can cause hypoglycemia
4. The InPen is compatible with Lilly Humalog ®, Novo Nordisk NovoRapid®, Novo Nordisk Fiasp® insulin cartridges

together, (the **Representations**).

The restricted representations must only be used with both of the following statements:

- A healthcare professional should assist in programming of the device prior to use, based on various patient-specific criteria and targets
- For additional product and safety information, please consult the Instructions for Use.

together, (the **Advisory Statements**).

(B) Medtronic Australasia Pty Ltd - Electronic insulin pen (ARTG 372085)

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 and Aged Care for the purposes of subsections 42DL(10) and 42DLB(7) of the Act.

Dated this 6th day of March 2023

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

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