Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by Nevro Medical Pty Ltd

I, Elizabeth Butt, as a delegate of the Secretary to the Department of Health, on receipt of an application from Nevro Medical Pty Ltd have approved under section 42DF of the *Therapeutic Goods Act 1989* (the **Act**) the restricted representations described in paragraph (**A**) below for use in consumer advertising of the product identified in paragraph (**B**):

(A) Representations to the effect that HF-10 may assist in the management of persistent lower limb pain associated with medically diagnosed diabetic peripheral neuropathy, which will always be accompanied by the following statements, prominently displayed or communicated,[1] and to the effect of the following:

- this product is not a first-line treatment for the pain associated with diabetic peripheral neuropathy; and
- surgery is required in order to use this product; and
- any surgical procedure carries risk; and
- talk to your health professional about whether this product may be suitable for you as part of your overall plan to manage diabetic peripheral neuropathy.

(B) Product marketed as "HF-10" under the following entry in the Australian Register of Therapeutic Goods (ARTG):

- Senza Omnia IPG kit – NIPG2500 – Stimulator, electrical, analgesic, spinal cord" (ARTG 330704) (the **Device**).

Dated this 16th Day of June 2021

Signed electronically

Elizabeth Butt
Delegate of the Secretary to the Department of Health
Advertising and Compliance Education and Policy Section
Regulatory Compliance Branch

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