Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by Mainstay Medical (Australia) Pty Ltd

I, Nicole McLay, as a delegate of the Secretary to the Department of Health, on receipt of an application from Mainstay Medical (Australia) Pty Ltd, 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)

- The ReActiv8 Implantable Pulse Generator device is indicated as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing. The device is intended for patients that have attempted medical management and at least one course of physical therapy (the '**Restricted Representation**).

- The Restricted Representation will only be used when accompanied with all the following statements, prominently displayed or communicated[1]:
    i. Patients should consult their healthcare professional to determine if the ReActiv8 Implantable Pulse Generator (IPG) device is right for them; and

    ii. Outcomes may vary for each patient. Patients should consult their healthcare professional about factors that could impact the level and timing of the effect; and

    iii. Patients must talk to their health professional about whether the ReActiv8 IPG device may be suitable as part of the overall plan to manage intractable chronic mechanical lower back pain; and

    iv. The ReActiv8 IPG device is not a first-line treatment for chronic mechanical lower back pain; and

    v. Surgery is required in order to use the ReActiv8 IPG device and any surgical procedure carries risk,

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

(B)

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

- ReActiv8 Implantable Pulse Generator - Implantable lumbar neuromuscular electrical stimulation system pulse generator (ARTG 327089)

Dated this 22nd day of April 2022.

Signed electronically

Nicole McLay
Delegate of the Secretary to the Department of Health
Regulatory Compliance Branch