



**Australian Government**

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**Department of Health, Disability and Ageing**  
Therapeutic Goods Administration

## **Mainstay Medical Australia Pty Ltd – ReActiv8 Implantable Pulse Generator (ARTG 478005)**

### ***Therapeutic Goods Act 1989***

### **Approval under section 42DF for use of restricted representations by Mainstay Medical Australia Pty Ltd**

I, Michael Shum, as a delegate of the Secretary to the Department of Health, Disability and Ageing, 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 advertisements for the product identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated<sup>1</sup> in the advertisement in which the restricted representations are used.

#### **(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 and associated physiological testing.

#### **(B)**

ReActiv8 Implantable Pulse Generator - Analgesic spinal cord electrical stimulation system pulse generator implantable (ARTG 478005)

#### **(C)**

- The device is intended for patients that have attempted medical management and at least one course of physical therapy
- ReActiv8 is an implantable device, and surgery is required to use the device and may carry surgical risks
- Patients should consult their healthcare professional to determine if ReActiv8 may be suitable for them.

Dated this 12th day of May 26

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<sup>1</sup> ***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

*Signed electronically*

Michael Shum

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

Education Policy and Guidance Section

Regulatory Compliance Branch