



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, Rowena Love, as a delegate of the Secretary to the Department of Health and Aged Care, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph (A), when used together and when used with all the statements identified in paragraph (B) in advertisements for the medical devices in paragraph (C).

- (A)**
1. The InterStim X™ implantable neurostimulator is indicated as an aid in the management of urinary and/or faecal incontinence.
 2. The InterStim X™ system is not a first-line treatment for urinary or faecal incontinence.
 3. The InterStim X™ system will not cure your urinary or faecal incontinence. However, it may reduce your symptoms to a tolerable level and allow you to resume many of your daily activities impacted by incontinence.

(B)

- Outcomes may vary for each patient. Patients should consult their healthcare professional to determine whether the InterStim X™ system is appropriate as part of their treatment plan.
- The device is intended for patients that have attempted pelvic floor physiotherapy and other medical management of their symptoms.
- Surgery is required in order to use this product, and any surgical procedure carries risk.

- (C)**
1. The InterStim X Clinician App A51300 – Multi-purpose electrical stimulation system programmer (ARTG number 402561);
 2. Patient Therapy App Model A52300 - Multi-purpose electrical stimulation system programmer (ARTG number 402562);

3. Handset with Communicator Model TH90Q02 - Multi-purpose electrical stimulation system programmer (ARTG number 419710); and

4. InterStim X Model 97800 - Implantable incontinence-control electrical stimulation system pulse generator (ARTG number 421914).

Dated this 9th day of January 2024

Signed electronically,

Rowena Love

Delegate of the Secretary to the Department of Health and Aged Care
Advertising and Compliance Education and Policy Section
Regulatory Compliance Branch