



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
Medistar 2 Pty Ltd as Trustee for the JVOT Family Trust T/a Medistar**

I, Michael Shum, 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), for use in advertising the product identified in paragraph (B) to consumers.

- (A)** In Australia, GammaCore is indicated for the treatment and/or prevention of primary headache conditions (such as migraine and cluster headache) in adults (the **Representation**).

The Representation will always be accompanied by the following advisory statements:

- GammaCore is available in Australia on authorisation by a registered healthcare professional.
- It is important to discuss your suitability for GammaCore nVNS therapy, with your healthcare professional.

- (B)** GammaCore - Migraine-therapy vagus nerve electrical stimulator (ARTG 355575)

Dated this 23rd day of October 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