



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Boston Scientific Pty Ltd – Vercise Genus™ Deep Brain Stimulation System

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Boston Scientific 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 Boston Scientific Pty Ltd, have approved under section 42DF of the Act the restricted representation described in paragraph **(A)**, for use in advertisements for the products identified in paragraph **(B)**, where all four advisory statements in paragraph **(C)** are prominently displayed or communicated in the advertisement in which the restricted representation described in paragraph **(A)** is used.

(A)

A representation to the effect that the DBS system may be used to treat motor symptoms associated with Parkinson's disease, essential tremor and dystonia in appropriately selected patients following specialist assessment.

(B)

DBS Lead Kit - Deep brain electrical stimulation system lead (ARTG 202017); Charger - Battery charger (ARTG 202018); 8 Contact Extension Kit - Electrode/lead, stimulator, implantable, neurological (ARTG 202034); Vercise Cartesia DBS Directional Lead Kit - Deep brain electrical stimulation system lead (ARTG 279186); Vercise M8 Adapter - Neural-tissue electrical stimulation lead adaptor (ARTG 281579); Vercise DBS Remote Control 3 - Multi-purpose electrical stimulation system programmer (ARTG 308577); 2x8 Contact Lead Extension Kit – Brain electrical stimulation system, antitremor (ARTG 363575); Vercise DBS Remote Control 4 - Multi-purpose electrical stimulation system programmer (ARTG 363576); Vercise DBS ETS 3 - Brain electrical stimulation system, antitremor (ARTG 363578); Vercise Genus P16 Implantable Pulse Generator Kit - Brain electrical stimulation system, antitremor (ARTG 400410); Vercise Genus R16 Implantable Pulse Generator Kit - Brain electrical stimulation system, antitremor (ARTG 400411); Vercise Genus P32 Implantable Pulse Generator Kit - Brain electrical stimulation system, antitremor (ARTG 400422); Vercise Genus R32 Implantable Pulse Generator Kit - Brain electrical stimulation system, antitremor (ARTG 400423); Vercise Adapter S8 - Neural-tissue electrical stimulation lead adaptor (ARTG 462220); Vercise™ Cartesia™ HX Directional Lead Kit - Deep brain electrical stimulation system lead (ARTG 476409); Vercise™ Cartesia™ X Directional Lead Kit - Deep brain electrical stimulation system lead (ARTG 476410); and 16-Contact Lead Extension Kit – Brain electrical stimulation system, antitremor (ARTG 487247).

(C)

- This product is not a first-line treatment.
- Surgery is required for use of the DBS system.

- Any surgical procedure carries risk.
- Talk to your healthcare professional about whether this product may be suitable for you as part of your overall plan to manage Parkinson's, essential tremor or dystonia.

Dated this 23rd day of September 26

Signed electronically

Michael Shum

Delegate of the Secretary to the Department of Health, Disability and Ageing
Education Policy and Guidance Section
Regulatory Compliance Branch