Public Summary

Summary for ARTG Entry:	476627	Abbott Medical Australia Pty Ltd - Liberta RC™ DBS IPG Model 62400 - Brain electrical stimulation system, antitremor

ARTG entry for	Medical Device Included Class III
Sponsor	Abbott Medical Australia Pty Ltd
Postal Address	299 Lane Cove Rd, Macquarie Park, NSW, 2113 Australia
ARTG Start Date	24/01/2025
Product Category	Medical Device Class III
Status	Active
Approval Area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address	Location Id
Abbott Medical	6901 Preston Road Plano, Texas, 75024 United States Of America	113253

Products

1 . Liberta RC™ DBS IPG Model 62400 - Brain electrical stimulation system, antitremor

Product Type	Single Device Product	**Effective Date**	24/01/2025

GMDN	37307 Brain electrical stimulation system, antitremor
Functional Description	The Liberta RC DBS IPG is a hermetically sealed cannister with an epoxy header containing two 8 channel lead ports; it is powered by a rechargeable lithium-ion battery and provides stimulation to targeted nuclei within the brain via compatible leads and extensions.
Intended Purpose	The Liberta RC™ Deep Brain Stimulation (DBS) System is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system and is indicated for the following conditions: Bilateral stimulation of the subthalamic nucleus (STN) or the internal globus pallidus (GPi) as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinson's disease that are not adequately controlled by medications. Unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability.
Variant information	Nil variant (as 1 device) 0

Specific Conditions

No Specific Conditions included on Record