Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	284637 ANZ-Medical Pty Ltd - Transcranial electrical stimulation system, continuous-current
ARTG entry for	Medical Device Included Class IIa
Sponsor	ANZ-Medical Pty Ltd
Postal Address	PO Box 6904, Silverwater, NSW, 1811 Australia
ARTG Start Date	16/01/2017
Product Category	Medical Device Class IIa
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
Soterix Medical Inc	237 W 35 St 1401 , NY, 10001 United States Of America

Products

1 . Transcranial electrical stimulation system, continuous-current

Product Type	Single Device Product	**Effective Date**	16/01/2017
GMDN	62056 Transcranial electrical stimulation system, continuous-current		
Intended Purpose	Transcranial Direct Current Stimulation (tDCS) is a non-invasive procedure in which a device sends a small Direct Current (DC) across the scalp to modulate brain function. The 1x1 tDCS Low-Intensity Stimulator sends a low-level current from the positive electrode, anode, to the negative electrode, cathode. When the extremely low level current passes from the anode to the cathode, it simultaneously increases the activity of the brain by the anode and decreases the activity of the brain near the cathode. The device is intended to treat different neurological and psychiatric disorders. In particular, tDCS increases spontaneous brain activity and metabolism in areas found to be hypoactive in patients suffering from major depressive disorder. Per application for pain, primary motor cortex tDCS interfers with perceptual processing of pain while prefrontal cortex stimulation modulates the affective reaction to painful experiences.		

Specific Conditions

· The sponsor must not import, supply or export the kind of medical device in Australia unless the information provided with the device (including labelling, instructions for use and any other technical and/or promotional material) clearly states that the device is intended for use strictly by qualified healthcare practitioners.
· The instructions for use must be provided with the device, and among other things, must include precautions that the use of the device for administration of transcranial direct current stimulation, where indicated for treatment of major depressive disorders in adults, it should only be undertaken following the recommendation of a psychiatrist or psychologist, with close monitoring by a healthcare practitioner, and where indicated for the treatment of chronic pain in adults, it should only be undertaken following the recommendation of a medical practitioner, psychiatrist, psychologist, physiotherapist, or pain specialist with close monitoring by a healthcare practitioner directly or remotely.

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