Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Cochlear Ltd

I, Elizabeth Butt, as a delegate of the Secretary to the Department of Health, on receipt of an application from Cochlear Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph (**A**), for use in consumer advertising of the **Device System** identified in paragraph (**B**):

(A) Representations to the effect that the Cochlear Osia System is indicated for patients with conductive, mixed hearing loss and single-sided sensorineural deafness (SSD), which will always be accompanied by the following statements, prominently displayed or communicated[1], on every piece of consumer advertising where the representation is used:

- Please seek advice from your health professional about treatments for hearing loss.
- The Cochlear Osia System is indicated for patients aged 10 years and above with up to 55 decibels sensorineural hearing loss.
- Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome.
- Patients should have sufficient bone quality and quantity to support successful implant placement.
- Surgery is required to use this product. Any surgical procedure carries risk.

(B) Cochlear Osia System (the **Device System**), which comprises of:

- Osia 2 Sound Processor Kit - Cochlear implant system sound processor (ARTG 375450) and;
- Cochlear Osia OSI200 Implant - Bone-conduction hearing implant system vibrator assembly (ARTG 379130)

Dated this 15th day of December 2021

Signed electronically

Elizabeth Butt
Delegate of the Secretary to the Department of Health
Advertising and Compliance Education and Policy Section
Regulatory Compliance Branch

[1] As defined in the applicable version of the Therapeutic Goods Advertising Code, as amended from time to time.

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