Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Advertising Approval: Cochlear Limited – Cochlear Osia OSI300 Implant - Bone-conduction hearing implant system vibrator assembly (ARTG 444958) - Osia 2(I) Sound Processor Kit - Cochlear implant system sound processor (ARTG 444959)

Therapeutic Goods Act 1989

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

I, Rowena Love, as a delegate of the Secretary to the Department of Health and Aged Care, on receipt of an application from Cochlear Limited, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representation described in paragraph (**A**), for use in advertisements for the product identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated[1] in the advertisement in which the restricted representations are used, subject to the conditions identified in paragraph **(D)**.

(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).

(B)

Cochlear Osia System which comprises of**:**

- Cochlear Osia OSI300 Implant - Bone-conduction hearing implant system vibrator assembly (ARTG 444958)
- Osia 2(I) Sound Processor Kit - Cochlear implant system sound processor (ARTG 444959)

(C)

- Please seek advice from your health professional about treatments for hearing loss.
- The Cochlear Osia System is indicated for patients aged 5 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.

[1] ***prominently displayed or communicated***, in relation to a statement in an advertisement, means:
(a) either:
(i) for a visual statement—easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or
(ii) for a spoken statement—able to be clearly heard and understood; and
(b) repeated as often as necessary to be noticed by a viewer or listener

(D)

- Advertisements in which any one of the Approved Representations is used must comply with the Therapeutic Goods Advertising Code (the Code).

Dated this 31st day of January 2025

Signed electronically

Rowena Love

Delegate of the Secretary to the Department of Health and Aged Care

Advertising and Compliance Education and Policy Section

Regulatory Compliance Branch