



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 288466 Cochlear Ltd - Fully-implantable middle ear implant system

ARTG entry for Medical Device Included (Export Only) Class 1
Sponsor Cochlear Ltd
Postal Address 1 University Avenue, MACQUARIE UNIVERSITY, NSW, 2109
Australia
ARTG Start Date 1/05/2017
Product Category Medical Device Class 1
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
Cochlear Ltd	1 University Avenue MACQUARIE UNIVERSITY, NSW, 2109 Australia	89600

Products

1 . Fully-implantable middle ear implant system

Product Type	Single Device Product	Effective Date	1/05/2017
GMDN	58991 Fully-implantable middle ear implant system		
Intended Purpose	These implants are prescription only, single use devices intended for long term implantation under the skin in the mastoid region of either side of the head.		

Specific Conditions

No Specific Conditions included on Record

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