



Benannt durch/ Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099



Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 078611 0135 Rev. 03

Manufacturer:

Cochlear Limited

1 University Avenue
Macquarie University NSW 2109
AUSTRALIA

SRN Manufacturer - AU-MF-000009890

Authorized Representative:

Cochlear Deutschland GmbH & Co. KG
Mailänder Straße 4 a, 30539 Hannover, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s)

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.

The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.

In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:G70 078611 0135 Rev. 03

Report No.: 713266579

Preceding Certificate No.: G70 078611 0135 Rev. 02

Valid from: 2023-08-04

Valid until: 2026-09-27

Date of Initial Issuance: 2021-09-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-08-04



EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
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No. G70 078611 0135 Rev. 03

Classification: Class III

Device Group: J0301 - COCHLEAR IMPLANTABLE DEVICES

Basic UDI-DI: 9321502CI632JR

Intended Purpose: The CI632 cochlear implant is intended to be used in combination with other devices as part of a cochlear implant system to provide hearing sensation via electrical stimulation of the auditory nerve.

Device(s): Cochlear™ Nucleus® CI632 cochlear implant with Slim Modiolar electrode; Model CI632

Classification: Class III

Device Group: J0301 - COCHLEAR IMPLANTABLE DEVICES

Basic UDI-DI: 9321502CI622JN

Intended Purpose: The CI622 cochlear implant is intended to be used in combination with other devices as part of a cochlear implant system to provide hearing sensation via electrical stimulation of the auditory nerve.

Device(s): Cochlear™ Nucleus® CI622 cochlear implant with Slim Straight electrode; Model CI622

Classification: Class III

Device Group: J0301 - COCHLEAR IMPLANTABLE DEVICES

Basic UDI-DI: 9321502CI624JS

Intended Purpose: The CI624 cochlear implant is intended to be used in combination with other devices as part of a cochlear implant system to provide hearing sensation via electrical stimulation of the auditory nerve.

Device(s): Cochlear™ Nucleus® CI624 cochlear implant with Slim 20 electrode; Model CI624



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No. G70 078611 0135 Rev. 03

Classification:	Class III
Device Group:	J0301 - COCHLEAR IMPLANTABLE DEVICES
Basic UDI-DI:	9321502CI612JK
Intended Purpose:	The CI612 cochlear implant is intended to be used in combination with other devices as part of a cochlear implant system to provide hearing sensation via electrical stimulation of the auditory nerve.
Device(s):	Cochlear™ Nucleus® CI612 cochlear implant with Contour Advance® electrode; Model CI612

The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2021-09-28	713213500	-
01	2023-01-30	713273169	-
02	2023-03-30	713227307	Supplemented: Device(s)/group of device(s) added
03	2023-08-04	713266579	Supplemented: Device(s)/group of device(s) added