Docusign Envelope ID: 258A7465-4A3E-8786-824A-E97294ACDCB6

EU Declaration of Conformity

Manufacturer:	Cochlear Limited 1 University Avenue Macquarie University NSW 2109 Australia Single Registration Number (SRN): AU-MF-000009890
Authorised Representative:	Cochlear Deutschland GmbH & Co. KG Mailänder Straße 4 a 30539 Hannover Germany Single Registration Number (SRN): DE-AR-000006034
Risk Class:	Class III
EMDN Code & Term:	J0380 - Auditory Active - Implantable Devices - Accessories
Product(s):	Refer to Schedule I for the list of applicable devices
Intended Purpose	Refer to Schedule II for the list of Intended Purposes per device
Conformity Assessment Procedure:	ANNEX IX – All Chapters Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation.
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraβe 65, 80339 München Germany Notified Body Identification No.: 0123
CE Certificate(s):	QMS Certificate issued under Annex IX, Chapter I: Certificate No.: G15 078611 0253 Revision: 00 Valid from: 2026-08-06 Valid until: 2031-08-05 Technical Assessment Certificate issued under Annex IX, Chapter II: Certificate No.: G70 078611 0215 Revision: 00 Valid from: 2025-01-13 Valid until: 2030-01-12
Common Specifications (CS):	None
Relevant Standards or other technical specifications required to be listed by regulation:	N/A

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The products covered by this declaration are in conformity with the following European Union legislation:

- Regulation (EU) 2017/745 on medical devices.
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
- Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and the conformity assessment route of Annex II. All essential radio test suites have been carried out and all products covered by the scope of this declaration are in conformity with all essential requirements of Directive 2014/53/EU.
- Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices.

The technical documentation relevant to the products covered by this declaration are kept at the manufacturer's address listed above.

I hereby confirm that this EU declaration of conformity is issued under the sole responsibility of the manufacturer, Cochlear Limited.

Authorised Signatory on behalf of Cochlear Limited and for the Person Responsible for Regulatory Compliance:

Signed by:
828A78CC59DD4EE...

Damien Rankin

Vice President Global Quality & Regulatory

Date: 11 August 2026

Place: Sydney, Australia

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Schedule I: Devices

Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	EMDN Code	GMDN code
Z60686	Cochlear Wired Programming Pod	N/A	N/A	N/A	9321502WiredProgPodP8	J0380	61462
Z594046	Wireless Programming Pod - CP800 Series - CP900 Series	N/A	N/A	N/A	9321502WirelessProgPodR4	J0380	61462
Z597944	Cochlear Wireless Programming Pod	N/A	N/A	N/A	9321502WirelessProgPodR4	J0380	61462
Z327114	Nucleus Programming Shoe with Cable	N/A	N/A	N/A	9321502CP900PShoeCable7A	J0380	61245
Z594640	Cochlear Programming Cable	N/A	N/A	N/A	9321502CP1000ProgCable5F	J0380	61245
Z544308	Kanso Programming Shoe Adaptor Cable	N/A	N/A	N/A	9321502KProgShoeAdCableK4	J0380	61245
P1320331	Kanso 2 Programming Adaptor Cable	N/A	N/A	N/A	9321502CP1150ProgCableBF	J0380	61245

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Schedule II: Intended Purposes

Cochlear Part (Catalogue) Number	Intended Purpose
Z60686	The Cochlear Wired Programming Pod is used to connect a processing unit to a computer running the programming software to enable communication between the fitting software and the processing unit.
Z594046	The Wireless Programming Pod is used to connect a processing unit to a computer running the programming software to enable communication between the fitting software and the processing unit.
Z597944	The Wireless Programming Pod is used to connect a processing unit to a computer running the programming software to enable communication between the fitting software and the processing unit.
Z327114	The programming shoe and cable is intended to provide a connection between a processing unit or sound processor and a programming pod.
Z594640	The programming shoe and cable is intended to provide a connection between a processing unit or sound processor and a programming pod.
Z544308	The programming shoe and cable is intended to provide a connection between a processing unit or sound processor and a programming pod.
P1320331	The programming shoe and cable is intended to provide a connection between a processing unit or sound processor and a programming pod.

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Change History

Version	Date	Change	Author
1	13-Jan-2025	Initial Introduction	MT
2	Refer to WC approval record	Added reference to Regulation (EU) 2021/2226 Re-signed following approval of SC24-09	CC
3	Refer to WC approval record	Update reference of the QMS Certificate issued under Annex IX, Chapter I Remove Trademark symbols	VI
4	Refer to WC approval record	Removal of Chapter III mention as it does not appear anymore on the new QMS certificate	VI