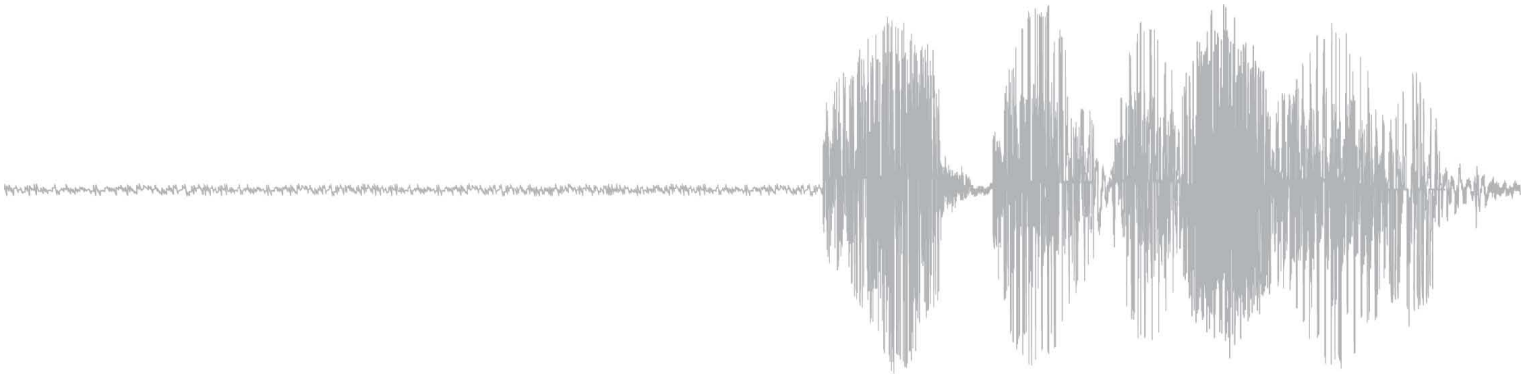

CI600 Series EU (MDR) Declaration of Conformity

D1817042

Version: 3
State: Approved (T+B)
Approver: Steven Kennedy (skennedy)
Date : 10 Aug 2023

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Hear now. And always

Cochlear®

EU Declaration of Conformity – CI600 Series Implants

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 and Term:	J0301 – Cochlear Implants
Products:	See attached Schedule of Products
Intended Purpose	See attached Table of Intended Purpose
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, Chapters I and III: Certificate No.: G12 078611 0117 Rev. 02 Valid from: 2023-01-30 Valid until: 2026-08-05 Technical Assessment Certificate issued under Annex IX, Chapter II: Certificate No.: G70 078611 0135 Rev. 03 Valid from: 2023-08-04 Valid until: 2026-09-27
Common Specifications (CS):	'None'
Relevant Standards or other technical specifications required to be listed by regulation:	N/A

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

- Regulation (EU) 2017/745 on 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:

DocuSigned by:

0AC55D29F40942D...

Steven Kennedy

Vice President Global Regulatory Affairs

Date: 04 August 2023

Place: Sydney, Australia

Schedule of Products

Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name	Option / Variant	Basic UDI-DI	GMDN Code
P783831	Cochlear™ Nucleus® CI632 cochlear implant with Slim Modiolar electrode	CI632	Same as product name	n/a	**9321502CI632JR**	47373
P1431676	Cochlear™ Nucleus® CI624 cochlear implant with Slim 20 electrode	CI624	Same as product name	n/a	**9321502CI624JS**	47373
P783829	Cochlear™ Nucleus® CI622 cochlear implant with Slim Straight electrode	CI622	Same as product name	n/a	**9321502CI622JN**	47373
P774600	Cochlear™ Nucleus® CI612 cochlear implant with Contour Advance® electrode	CI612	Same as product name	n/a	**9321502CI612JK**	47373

Table of Intended Purpose

Cochlear Part (Catalogue) Number	Product Name
P783831	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.
P1431676	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.
P783829	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.
P774600	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.

Change History

Version	Date	Change	Author
1	05 Oct 2021	Initial Introduction	Sally Jennings
2	17 May 2023	Addition of CI622 and CI624 to DoC	Sally Jennings
3	04 Aug 2023	Addition of CI612 to DoC	Clément Chaumont