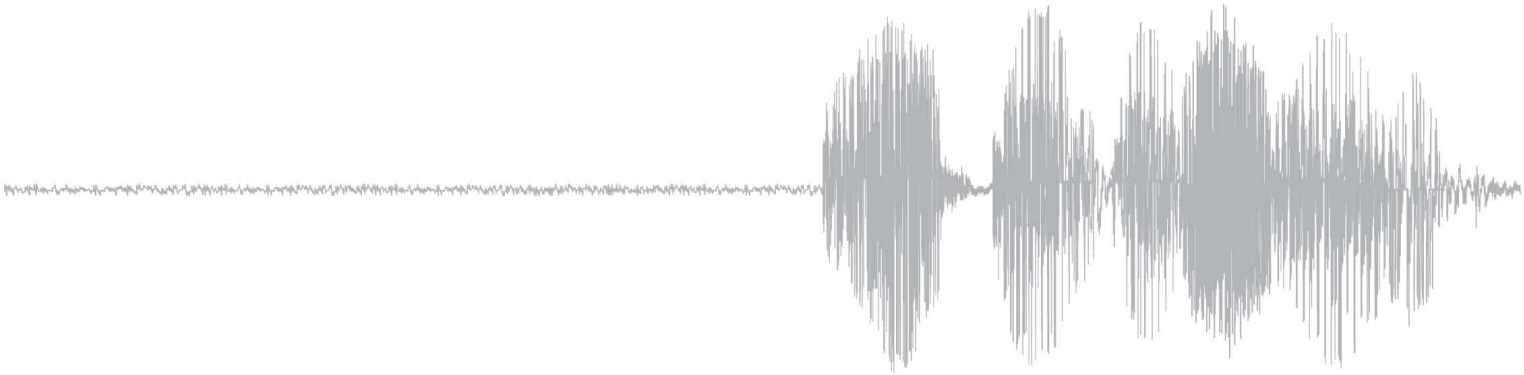

Nucleus 8 Processing Unit EU MDR Declaration of Conformity

D1891890

Version: 6
State: Approved (T+B)
Approver: Marcus Ignacio (MIgnacio)
Date : 26 Feb 2025

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Hear now. And always

Cochlear®

Number of pages (include Coversheet): 5

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):	See attached Schedule of Products
Intended Purpose:	The processing unit is intended to be used in combination with other devices as part of a hearing implant system to provide hearing sensation. The processing unit converts sounds into electrical signals, which it sends, via a coil, to an implant. The processing unit also provides power to the implant. When used in combination with an audio receiver, the sound processor also delivers sound to the ear canal in recipients with residual hearing.
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 Revision: 02 Valid from: 2023-01-30 Valid until: 2026-08-05 Technical Assessment Certificate issued under Annex IX, Chapter II: Certificate No.: G70 078611 0143 Revision: 01 Valid from: 2023-01-30 Valid until: 2027-07-20

Common Specifications (CS):	None
Relevant Standards or other technical specifications required to be listed by regulation:	**Directive 2014/53/EU, Article 3:** **1(a): Health and Safety of the User** − EN 60601-1:2006 / A12:2014 / A2: 2021 **1(b): Electromagnetic Compatibility** − EN 60601-1-2:2015 + A1:2021); EN 301 489-1 v2.2.3; EN 301 489-3 v2.3.2; EN 301 489-17 v3.2.5 **2: Effective use of spectrum allocated** − EN 300 328 v2.2.2 and EN 300 330 v.2.1.1

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

- Regulation (EU) 2017/745 on medical devices.
- 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.
- 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.
- 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 — Date: 18 February 2025

Vice President Global Quality & Regulatory — Place: Sydney, Australia

Schedule of Products

Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	GMDN code
P1840233	Cochlear™ Nucleus® 8 Processing Unit	CP1110	N/A	Black	9321502CP1110PU4D	47374
P1840332	Cochlear™ Nucleus® 8 Processing Unit	CP1110	N/A	Brown	9321502CP1110PU4D	47374
P1840542	Cochlear™ Nucleus® 8 Processing Unit	CP1110	N/A	Grey	9321502CP1110PU4D	47374
P1840403	Cochlear™ Nucleus® 8 Processing Unit	CP1110	N/A	Sand	9321502CP1110PU4D	47374
P1840723	Cochlear™ Nucleus® 8 Processing Unit	CP1110	N/A	White	9321502CP1110PU4D	47374
P1840111	Cochlear™ Nucleus® 8 Processing Unit	CP1110	N/A	Silver	9321502CP1110PU4D	47374

Change History

Version	Date	Change	Author
1	26 Jul 2022	Initial Introduction	PM
2	23 Jan 2023	Update template and Purpose Statement.	PM
3	03 Mar 2023	Update EC Rep address.	PM
4	28 Feb 2024	Update for Blank SP approval.	CN
5	22 Nov 2024	Update RED compliance details	JFJ
6	Refer to WC approval record	Added reference to Regulation (EU) 2021/2226 Re-signed following approval of SC24-09	CC