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: 2023-01-23 Valid until: 2026-08-05 Technical Assessment Certificate issued under Annex IX, Chapter II: Certificate No.: G70 078611 0123 Revision: 02 Valid from: 2023-01-30 Valid until: 2026-01-21

Common Specifications (CS):	None
Relevant Standards or other technical specifications required to be listed by regulation:	**3.1 (a): Health and Safety of the User −** EN 60601-1:2006 + Corr.1:2010 + A11:2011 + A12:2014 (IEC 60601-1:2005(Third Edition) + Corr.1:2006 + Corr.2:2007+A1:2012) **3.1 (b): Electromagnetic Compatibility −** EN 60601-1-2:2015, (IEC 60601-1-2:2014); EN 301 489-1 v2.1.1; EN 301 489-17 v3.1.1 **3.2: Effective use of spectrum allocated −** EN 300 328 v2.2.2

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.

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:
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Steven Kennedy — Date: 15 February 2023

Vice President Global Regulatory Affairs — Place: Sydney, Australia

Schedule of Products

Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	GMDN code
Z482005	Nucleus® 7 Processing Unit	CP1000	N/A	Black, Platinum Detail	9321502CP1000PU3T	47374
Z482006	Nucleus® 7 Processing Unit	CP1000	N/A	Brown	9321502CP1000PU3T	47374
Z482007	Nucleus® 7 Processing Unit	CP1000	N/A	Grey	9321502CP1000PU3T	47374
Z482008	Nucleus® 7 Processing Unit	CP1000	N/A	Sand	9321502CP1000PU3T	47374
Z482009	Nucleus® 7 Processing Unit	CP1000	N/A	Black, Golden Detail	9321502CP1000PU3T	47374
Z544559	Nucleus® 7 Processing Unit	CP1000	N/A	White	9321502CP1000PU3T	47374

Change History

Version	Date	Change	Author
1	22 Jan 2021	Initial Introduction	Natalie Dubs
2	20 May 2021	Approval of N7R5 (CN20-04), certificate change to Rev. 1	Rick Rosa
3	9 Aug 2021	Added SRN and QMS certificate numbers	Natalie Dubs
4	7 Feb 2022	Update revision number of QMS certificate	Tanaya Gope
5	15 Feb 2022	Update Template Version (Include Intended Purpose, Update EC Rep Address)	Nils Bown