Docusign Envelope ID: CCBE1252-5D38-80D6-83E0-CAACCAE807D4

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):	Nucleus 8 Sound Processor and Accessories (Refer to Schedule I for the list of applicable devices)
Intended Purpose:	Nucleus 8 Sound Processor and Accessories (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 0143 Revision: 03 Valid from: 2025-12-12 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 (N8 Sound Processor only) EN 300 330 v.2.1.1

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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 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:

Signed by:

780E62E3A2E546E...

Damien Rankin

Vice President Global Quality and Regulatory

Date: 03 Sep 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
Battery modules (Cover, Holder, Rechargeable)							
P1840233	Cochlear Nucleus 8 Processing Unit	CP1110	N/A	Black	9321502CP1110PU4D	J0380	47374
P1840332	Cochlear Nucleus 8 Processing Unit	CP1110	N/A	Brown	9321502CP1110PU4D	J0380	47374
P1840542	Cochlear Nucleus 8 Processing Unit	CP1110	N/A	Grey	9321502CP1110PU4D	J0380	47374
P1840403	Cochlear Nucleus 8 Processing Unit	CP1110	N/A	Sand	9321502CP1110PU4D	J0380	47374
P1840723	Cochlear Nucleus 8 Processing Unit	CP1110	N/A	White	9321502CP1110PU4D	J0380	47374
P1840111	Cochlear Nucleus 8 Processing Unit	CP1110	N/A	Silver	9321502CP1110PU4D	J0380	47374
Battery modules (Cover, Holder, Rechargeable)							
Z491369	Cochlear Battery Holder	N/A	N/A	CP1000, CP1001, CP1002, Nucleus 8	9321502CP1000BatHolderRK	J0380	58185
P1840613	Cochlear Battery Cover	BC3	N/A	Black	9321502CP1110BatCoverKZ	J0380	58185
P1840716	Cochlear Battery Cover	BC3	N/A	Brown	9321502CP1110BatCoverKZ	J0380	58185
P1840736	Cochlear Battery Cover	BC3	N/A	Grey	9321502CP1110BatCoverKZ	J0380	58185
P1840738	Cochlear Battery Cover	BC3	N/A	Sand	9321502CP1110BatCoverKZ	J0380	58185
P1840758	Cochlear Battery Cover	BC3	N/A	White	9321502CP1110BatCoverKZ	J0380	58185
P1840741	Cochlear Battery Cover	BC3	N/A	Silver	9321502CP1110BatCoverKZ	J0380	58185
P1757683	Cochlear Power Extend Battery Module	N/A	N/A	Black	9321502CP1110RechBatQT	J0380	34158
P1757684	Cochlear Power Extend Battery Module	N/A	N/A	Brown	9321502CP1110RechBatQT	J0380	34158
P1757686	Cochlear Power Extend Battery Module	N/A	N/A	Grey	9321502CP1110RechBatQT	J0380	34158
P1757664	Cochlear Power Extend Battery Module	N/A	N/A	Sand	9321502CP1110RechBatQT	J0380	34158
P1757666	Cochlear Power Extend Battery Module	N/A	N/A	White	9321502CP1110RechBatQT	J0380	34158

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Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	EMDN Code	GMDN code
P1757665	Cochlear Power Extend Battery Module	N/A	N/A	Silver	9321502CP1110RechBatQT	J0380	34158
P1757689	Cochlear Compact Battery Module	N/A	N/A	Black	9321502CP1110RechBatQT	J0380	34158
P1757667	Cochlear Compact Battery Module	N/A	N/A	Brown	9321502CP1110RechBatQT	J0380	34158
P1757690	Cochlear Compact Battery Module	N/A	N/A	Grey	9321502CP1110RechBatQT	J0380	34158
P1757669	Cochlear Compact Battery Module	N/A	N/A	Sand	9321502CP1110RechBatQT	J0380	34158
P1757697	Cochlear Compact Battery Module	N/A	N/A	White	9321502CP1110RechBatQT	J0380	34158
P1757696	Cochlear Compact Battery Module	N/A	N/A	Silver	9321502CP1110RechBatQT	J0380	34158
P1757671	Cochlear Power Compact Battery Module	N/A	N/A	Black	9321502CP1110RechBatQT	J0380	34158
P1757701	Cochlear Power Compact Battery Module	N/A	N/A	Brown	9321502CP1110RechBatQT	J0380	34158
P1757675	Cochlear Power Compact Battery Module	N/A	N/A	Grey	9321502CP1110RechBatQT	J0380	34158
P1757676	Cochlear Power Compact Battery Module	N/A	N/A	Sand	9321502CP1110RechBatQT	J0380	34158
P1757677	Cochlear Power Compact Battery Module	N/A	N/A	White	9321502CP1110RechBatQT	J0380	34158
P1757702	Cochlear Power Compact Battery Module	N/A	N/A	Silver	9321502CP1110RechBatQT	J0380	34158
Magnets							
P1840452	Cochlear Magnet	N/A	N/A	Silver 5(I)	9321502CP1000MagnetTA	J0380	62944
P1840728	Cochlear Magnet	N/A	N/A	Silver, 6M	9321502CP1000MagnetTA	J0380	62944
P1840730	Cochlear Magnet	N/A	N/A	Silver, 5M	9321502CP1000MagnetTA	J0380	62944
P1840731	Cochlear Magnet	N/A	N/A	Silver, 4M	9321502CP1000MagnetTA	J0380	62944
P1840732	Cochlear Magnet	N/A	N/A	Silver, 3M	9321502CP1000MagnetTA	J0380	62944
P1840735	Cochlear Magnet	N/A	N/A	Silver, 2M	9321502CP1000MagnetTA	J0380	62944
P1840737	Cochlear Magnet	N/A	N/A	Silver 4(I)	9321502CP1000MagnetTA	J0380	62944
P1840739	Cochlear Magnet	N/A	N/A	Silver, 3(I)	9321502CP1000MagnetTA	J0380	62944
P1840740	Cochlear Magnet	N/A	N/A	Silver, 2(I)	9321502CP1000MagnetTA	J0380	62944

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Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	EMDN Code	GMDN code
P1840742	Cochlear Magnet	N/A	N/A	Silver, 1(I)	9321502CP1000MagnetTA	J0380	62944
P1840743	Cochlear Magnet	N/A	N/A	Silver, 1/2 (I)	9321502CP1000MagnetTA	J0380	62944
P1840751	Cochlear Magnet	N/A	N/A	Silver, 1M	9321502CP1000MagnetTA	J0380	62944
P1840752	Cochlear Magnet Reverse Polarity	N/A	N/A	Silver, 6(R)	9321502CP1000MagnetTA	J0380	62944
P1840753	Cochlear Magnet Reverse Polarity	N/A	N/A	Silver, 5(R)	9321502CP1000MagnetTA	J0380	62944
P1840754	Cochlear Magnet Reverse Polarity	N/A	N/A	Silver, 4(R)	9321502CP1000MagnetTA	J0380	62944
P1840755	Cochlear Magnet Reverse Polarity	N/A	N/A	Silver, 3(R)	9321502CP1000MagnetTA	J0380	62944
P1840756	Cochlear Magnet Reverse Polarity	N/A	N/A	Silver, 2(R)	9321502CP1000MagnetTA	J0380	62944
P1840757	Cochlear Magnet Reverse Polarity	N/A	N/A	Silver, 1(R)	9321502CP1000MagnetTA	J0380	62944
P1840759	Cochlear Magnet	N/A	N/A	Silver, 1/2M	9321502CP1000MagnetTA	J0380	62944
P1840760	Cochlear Magnet Reverse Polarity	N/A	N/A	Silver, 1/2(R)	9321502CP1000MagnetTA	J0380	62944
P1473233	Cochlear Magnet	N/A	N/A	Brown, 1/2(I)	9321502CP1000MagnetTA	J0380	62944
P1473235	Cochlear Magnet	N/A	N/A	White, 1(I)	9321502CP1000MagnetTA	J0380	62944
P1473237	Cochlear Magnet	N/A	N/A	Black, 1(I)	9321502CP1000MagnetTA	J0380	62944
P1473238	Cochlear Magnet	N/A	N/A	Grey, 1(I)	9321502CP1000MagnetTA	J0380	62944
P1473239	Cochlear Magnet	N/A	N/A	Brown, 2(I)	9321502CP1000MagnetTA	J0380	62944
P1473240	Cochlear Magnet	N/A	N/A	White, 2(I)	9321502CP1000MagnetTA	J0380	62944
P1473243	Cochlear Magnet	N/A	N/A	Grey, 4(I)	9321502CP1000MagnetTA	J0380	62944
P1473245	Cochlear Magnet	N/A	N/A	Grey, 2(I)	9321502CP1000MagnetTA	J0380	62944
P1473246	Cochlear Magnet	N/A	N/A	Black, 1/2(I)	9321502CP1000MagnetTA	J0380	62944
P1473247	Cochlear Magnet	N/A	N/A	Sand, 3(I)	9321502CP1000MagnetTA	J0380	62944
P1473250	Cochlear Magnet	N/A	N/A	Black, 2(I)	9321502CP1000MagnetTA	J0380	62944
P1473252	Cochlear Magnet	N/A	N/A	White, 3(I)	9321502CP1000MagnetTA	J0380	62944

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Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	EMDN Code	GMDN code
P1473253	Cochlear Magnet	N/A	N/A	Sand, 1(I)	9321502CP1000MagnetTA	J0380	62944
P1473255	Cochlear Magnet	N/A	N/A	Sand, 2(I)	9321502CP1000MagnetTA	J0380	62944
P1473257	Cochlear Magnet	N/A	N/A	Grey, 1/2(I)	9321502CP1000MagnetTA	J0380	62944
P1473258	Cochlear Magnet	N/A	N/A	White, 4(I)	9321502CP1000MagnetTA	J0380	62944
P1473262	Cochlear Magnet	N/A	N/A	Sand, 4(I)	9321502CP1000MagnetTA	J0380	62944
P1473263	Cochlear Magnet	N/A	N/A	Brown, 4(I)	9321502CP1000MagnetTA	J0380	62944
P1473269	Cochlear Magnet	N/A	N/A	White, 1/2(I)	9321502CP1000MagnetTA	J0380	62944
P1473272	Cochlear Magnet	N/A	N/A	Brown, 1(I)	9321502CP1000MagnetTA	J0380	62944
P1473277	Cochlear Magnet	N/A	N/A	Black, 4(I)	9321502CP1000MagnetTA	J0380	62944
P1473283	Cochlear Magnet	N/A	N/A	Black, 3(I)	9321502CP1000MagnetTA	J0380	62944
P1473285	Cochlear Magnet	N/A	N/A	Grey, 3(I)	9321502CP1000MagnetTA	J0380	62944
P1473289	Cochlear Magnet	N/A	N/A	Sand, 1/2(I)	9321502CP1000MagnetTA	J0380	62944
P1473296	Cochlear Magnet	N/A	N/A	Brown, 3(I)	9321502CP1000MagnetTA	J0380	62944
P1623190	Cochlear Magnet	N/A	N/A	Grey, 5(I)	9321502CP1000MagnetTA	J0380	62944
P1623191	Cochlear Magnet	N/A	N/A	Sand, 5(I)	9321502CP1000MagnetTA	J0380	62944
P1623192	Cochlear Magnet	N/A	N/A	White, 5(I)	9321502CP1000MagnetTA	J0380	62944
P1623215	Cochlear Magnet	N/A	N/A	Black, 5(I)	9321502CP1000MagnetTA	J0380	62944
P1623216	Cochlear Magnet	N/A	N/A	Brown, 5(I)	9321502CP1000MagnetTA	J0380	62944
P715025	Cochlear Magnet Reverse Polarity	N/A	N/A	Sand, 1/2(R)	9321502CP1000MagnetTA	J0380	62944
P715027	Cochlear Magnet Reverse Polarity	N/A	N/A	Black, 1/2(R)	9321502CP1000MagnetTA	J0380	62944
P715029	Cochlear Magnet Reverse Polarity	N/A	N/A	Brown, 1/2(R)	9321502CP1000MagnetTA	J0380	62944
P715030	Cochlear Magnet Reverse Polarity	N/A	N/A	Grey, 1/2(R)	9321502CP1000MagnetTA	J0380	62944
P715031	Cochlear Magnet Reverse Polarity	N/A	N/A	White, 1/2(R)	9321502CP1000MagnetTA	J0380	62944

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Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	EMDN Code	GMDN code
P715032	Cochlear Magnet Reverse Polarity	N/A	N/A	Sand, 1(R)	9321502CP1000MagnetTA	J0380	62944
P715033	Cochlear Magnet Reverse Polarity	N/A	N/A	Black, 1(R)	9321502CP1000MagnetTA	J0380	62944
P715035	Cochlear Magnet Reverse Polarity	N/A	N/A	Brown, 1(R)	9321502CP1000MagnetTA	J0380	62944
P715036	Cochlear Magnet Reverse Polarity	N/A	N/A	Grey, 1(R)	9321502CP1000MagnetTA	J0380	62944
P715037	Cochlear Magnet Reverse Polarity	N/A	N/A	White, 1(R)	9321502CP1000MagnetTA	J0380	62944
P715039	Cochlear Magnet Reverse Polarity	N/A	N/A	Sand, 2(R)	9321502CP1000MagnetTA	J0380	62944
P715040	Cochlear Magnet Reverse Polarity	N/A	N/A	Black, 2(R)	9321502CP1000MagnetTA	J0380	62944
P715042	Cochlear Magnet Reverse Polarity	N/A	N/A	Brown, 2(R)	9321502CP1000MagnetTA	J0380	62944
P715043	Cochlear Magnet Reverse Polarity	N/A	N/A	Grey, 2(R)	9321502CP1000MagnetTA	J0380	62944
P715044	Cochlear Magnet Reverse Polarity	N/A	N/A	White, 2(R)	9321502CP1000MagnetTA	J0380	62944
P715045	Cochlear Magnet Reverse Polarity	N/A	N/A	Sand, 3(R)	9321502CP1000MagnetTA	J0380	62944
P715046	Cochlear Magnet Reverse Polarity	N/A	N/A	Black, 3(R)	9321502CP1000MagnetTA	J0380	62944
P715047	Cochlear Magnet Reverse Polarity	N/A	N/A	Brown, 3(R)	9321502CP1000MagnetTA	J0380	62944
P715048	Cochlear Magnet Reverse Polarity	N/A	N/A	Grey, 3(R)	9321502CP1000MagnetTA	J0380	62944
P715049	Cochlear Magnet Reverse Polarity	N/A	N/A	White, 3(R)	9321502CP1000MagnetTA	J0380	62944
P715050	Cochlear Magnet Reverse Polarity	N/A	N/A	Sand, 4(R)	9321502CP1000MagnetTA	J0380	62944
P715051	Cochlear Magnet Reverse Polarity	N/A	N/A	Black, 4(R)	9321502CP1000MagnetTA	J0380	62944
P715052	Cochlear Magnet Reverse Polarity	N/A	N/A	Brown, 4(R)	9321502CP1000MagnetTA	J0380	62944
P715053	Cochlear Magnet Reverse Polarity	N/A	N/A	Grey, 4(R)	9321502CP1000MagnetTA	J0380	62944
P715054	Cochlear Magnet Reverse Polarity	N/A	N/A	White, 4(R)	9321502CP1000MagnetTA	J0380	62944
P715056	Cochlear Magnet Reverse Polarity	N/A	N/A	Sand, 5(R)	9321502CP1000MagnetTA	J0380	62944
P715057	Cochlear Magnet Reverse Polarity	N/A	N/A	Black, 5(R)	9321502CP1000MagnetTA	J0380	62944
P715061	Cochlear Magnet Reverse Polarity	N/A	N/A	Brown, 5(R)	9321502CP1000MagnetTA	J0380	62944

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Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	EMDN Code	GMDN code
P715063	Cochlear Magnet Reverse Polarity	N/A	N/A	Grey, 5(R)	9321502CP1000MagnetTA	J0380	62944
P715064	Cochlear Magnet Reverse Polarity	N/A	N/A	White, 5(R)	9321502CP1000MagnetTA	J0380	62944
P715065	Cochlear Magnet Reverse Polarity	N/A	N/A	Sand, 6(R)	9321502CP1000MagnetTA	J0380	62944
P715066	Cochlear Magnet Reverse Polarity	N/A	N/A	Black, 6(R)	9321502CP1000MagnetTA	J0380	62944
P715067	Cochlear Magnet Reverse Polarity	N/A	N/A	Brown, 6(R)	9321502CP1000MagnetTA	J0380	62944
P715068	Cochlear Magnet Reverse Polarity	N/A	N/A	Grey, 6(R)	9321502CP1000MagnetTA	J0380	62944
P715070	Cochlear Magnet Reverse Polarity	N/A	N/A	White, 6(R)	9321502CP1000MagnetTA	J0380	62944
Z586124	Cochlear Magnet	N/A	N/A	Sand, 1/2M	9321502CP1000MagnetTA	J0380	62944
Z586125	Cochlear Magnet	N/A	N/A	Black, 1/2M	9321502CP1000MagnetTA	J0380	62944
Z586126	Cochlear Magnet	N/A	N/A	Brown, 1/2M	9321502CP1000MagnetTA	J0380	62944
Z586128	Cochlear Magnet	N/A	N/A	Grey, 1/2M	9321502CP1000MagnetTA	J0380	62944
Z586135	Cochlear Magnet	N/A	N/A	White, 1/2M	9321502CP1000MagnetTA	J0380	62944
Z586137	Cochlear Magnet	N/A	N/A	Sand, 1M	9321502CP1000MagnetTA	J0380	62944
Z586139	Cochlear Magnet	N/A	N/A	Black, 1M	9321502CP1000MagnetTA	J0380	62944
Z586141	Cochlear Magnet	N/A	N/A	Brown, 1M	9321502CP1000MagnetTA	J0380	62944
Z586145	Cochlear Magnet	N/A	N/A	Grey, 1M	9321502CP1000MagnetTA	J0380	62944
Z586146	Cochlear Magnet	N/A	N/A	White, 1M	9321502CP1000MagnetTA	J0380	62944
Z586147	Cochlear Magnet	N/A	N/A	Sand, 2M	9321502CP1000MagnetTA	J0380	62944
Z586148	Cochlear Magnet	N/A	N/A	Black, 2M	9321502CP1000MagnetTA	J0380	62944
Z586149	Cochlear Magnet	N/A	N/A	Brown, 2M	9321502CP1000MagnetTA	J0380	62944
Z586150	Cochlear Magnet	N/A	N/A	Grey, 2M	9321502CP1000MagnetTA	J0380	62944
Z586151	Cochlear Magnet	N/A	N/A	White, 2M	9321502CP1000MagnetTA	J0380	62944
Z586152	Cochlear Magnet	N/A	N/A	Sand, 3M	9321502CP1000MagnetTA	J0380	62944

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Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	EMDN Code	GMDN code
Z586153	Cochlear Magnet	N/A	N/A	Black, 3M	9321502CP1000MagnetTA	J0380	62944
Z586154	Cochlear Magnet	N/A	N/A	Brown, 3M	9321502CP1000MagnetTA	J0380	62944
Z586155	Cochlear Magnet	N/A	N/A	Grey, 3M	9321502CP1000MagnetTA	J0380	62944
Z586156	Cochlear Magnet	N/A	N/A	White, 3M	9321502CP1000MagnetTA	J0380	62944
Z586157	Cochlear Magnet	N/A	N/A	Sand, 4M	9321502CP1000MagnetTA	J0380	62944
Z586158	Cochlear Magnet	N/A	N/A	Black, 4M	9321502CP1000MagnetTA	J0380	62944
Z586160	Cochlear Magnet	N/A	N/A	Brown, 4M	9321502CP1000MagnetTA	J0380	62944
Z586161	Cochlear Magnet	N/A	N/A	Grey, 4M	9321502CP1000MagnetTA	J0380	62944
Z586162	Cochlear Magnet	N/A	N/A	White, 4M	9321502CP1000MagnetTA	J0380	62944
Z586163	Cochlear Magnet	N/A	N/A	Sand, 5M	9321502CP1000MagnetTA	J0380	62944
Z586164	Cochlear Magnet	N/A	N/A	Black, 5M	9321502CP1000MagnetTA	J0380	62944
Z586165	Cochlear Magnet	N/A	N/A	Brown, 5M	9321502CP1000MagnetTA	J0380	62944
Z586167	Cochlear Magnet	N/A	N/A	Grey, 5M	9321502CP1000MagnetTA	J0380	62944
Z586168	Cochlear Magnet	N/A	N/A	White, 5M	9321502CP1000MagnetTA	J0380	62944
Z586169	Cochlear Magnet	N/A	N/A	Sand, 6M	9321502CP1000MagnetTA	J0380	62944
Z586170	Cochlear Magnet	N/A	N/A	Black, 6M	9321502CP1000MagnetTA	J0380	62944
Z586171	Cochlear Magnet	N/A	N/A	Brown, 6M	9321502CP1000MagnetTA	J0380	62944
Z586172	Cochlear Magnet	N/A	N/A	Grey, 6M	9321502CP1000MagnetTA	J0380	62944
Z586173	Cochlear Magnet	N/A	N/A	White, 6M	9321502CP1000MagnetTA	J0380	62944
Electrical and electronic accessories							
P1842636	Cochlear Y Battery Charger	YC2	N/A	White	9321502CP1110YBatCharge7J	J0380	17115
P1842635	Cochlear USB Battery Charger	UC2	N/A	White	9321502CP1110UBatCharge3W	J0380	17115
Z569903	Cochlear Remote Control	CR310	N/A	N/A	9321502CR310KX	J0380	57885

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Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	EMDN Code	GMDN code
Water-safe accessories							
P1840596	Cochlear Aqua+	N/A	N/A	Power Extend	9321502CP1110AquaPlusX8	J0380	61152
P1840593	Cochlear Aqua+	N/A	N/A	Compact	9321502CP1110AquaPlusX8	J0380	61152
Retention Accessories							
P1840267	Cochlear Earhook	EH2	N/A	Small	9321502CP1110EarhookUF	J0380	61243
P1840269	Cochlear Earhook	EH2	N/A	Medium	9321502CP1110EarhookUF	J0380	61243
P1840271	Cochlear Earhook	EH2	N/A	Large	9321502CP1110EarhookUF	J0380	61243
P1840434	Cochlear Tamper Resistant Earhook	TR2	N/A	N/A	9321502CP1110EarhookUF	J0380	61243
P1840351	Cochlear Hugfit	HF2	N/A	Small	9321502CP1110HugfitYK	J0380	61243
P1840295	Cochlear Hugfit	HF2	N/A	Extra Small	9321502CP1110HugfitYK	J0380	61243
P1840286	Cochlear Hugfit	HF2	N/A	Extra Extra Small	9321502CP1110HugfitYK	J0380	61243
P1840353	Cochlear Hugfit	HF2	N/A	Medium	9321502CP1110HugfitYK	J0380	61243
P1840355	Cochlear Hugfit	HF2	N/A	Large	9321502CP1110HugfitYK	J0380	61243
P1840372	Cochlear Snugfit	SF2	N/A	Small	9321502CP1110Snugfit8N	J0380	61243
P1840394	Cochlear Snugfit	SF2	N/A	Medium	9321502CP1110Snugfit8N	J0380	61243
P1840430	Cochlear Snugfit	SF2	N/A	Large	9321502CP1110Snugfit8N	J0380	61243
P1840480	Cochlear Earmould Adaptor	EA2	N/A	N/A	9321502CP1110EAdaptorAD	J0380	61243
P1840509	Cochlear Koala Clip	KC3	N/A	N/A	9321502CP1110KClipXZ	J0380	61244
P706992	Cochlear Headworn Adaptor	N/A	N/A	Right	9321502CP1000HAdaptorAA	J0380	61244
Z544861	Cochlear Headworn Adaptor	N/A	N/A	Left	9321502CP1000HAdaptorAA	J0380	61244
P1335209	Cochlear BTE Headband	N/A	N/A	XS, Vanilla	9321502CP1000HeadbandKK	J0380	61244
P1335210	Cochlear BTE Headband	N/A	N/A	XS, Grey	9321502CP1000HeadbandKK	J0380	61244
P1335211	Cochlear BTE Headband	N/A	N/A	XS, Black	9321502CP1000HeadbandKK	J0380	61244

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Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	EMDN Code	GMDN code
P1335212	Cochlear BTE Headband	N/A	N/A	S, Vanilla	9321502CP1000HeadbandKK	J0380	61244
P1335213	Cochlear BTE Headband	N/A	N/A	S, Grey	9321502CP1000HeadbandKK	J0380	61244
P1335214	Cochlear BTE Headband	N/A	N/A	S, Black	9321502CP1000HeadbandKK	J0380	61244
Adaptation accessories							
P1191447	Cochlear Coil Spacer	N/A	N/A	N/A	9321502CP1000CoilSpacerMX	J0380	61242
P793406	Cochlear SoftWear pad	N/A	N/A	N/A	9321502SoftWearPadW8	J0380	65086
P793408	Cochlear SoftWear pad	N/A	N/A	N/A	9321502SoftWearPadW8	J0380	65086

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Schedule II: Intended Purposes

Cochlear Part (Catalogue) Number	Intended Purpose
Nucleus 8 Processing Units	
Cochlear Nucleus 8 Processing Unit: P1840233, P1840332, P1840542, P1840403, P1840723, P1840111	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.
Battery modules (Cover, Holder, Rechargeable)	
Cochlear Battery Holder: Z491369	The battery is intended to supply power to a processing unit as part of a hearing implant system.
Cochlear Battery Cover (BC3): P1840613, P1840716, P1840736, P1840738, P1840758, P1840741	
Cochlear Compact Battery Module: P1757689, P1757667, P1757690, P1757669, P1757697, P1757696	
Cochlear Power Compact Battery Module: P1757671, P1757701, P1757675, P1757676, P1757677, P1757702	
Cochlear Power Extend Battery Module: P1757683, P1757684, P1757686, P1757664, P1757666, P1757665	
Magnets	
Cochlear Magnet: P1840452, P1840728, P1840730, P1840731, P1840732, P1840735, P1840737, P1840739, P1840740, P1840742, P1840743, P1840751, P1840759, P1473233, P1473235, P1473237, P1473238, P1473239, P1473240, P1473243, P1473245, P1473246, P1473247, P1473250, P1473252, P1473253, P1473255, P1473257, P1473258, P1473262, P1473263, P1473269, P1473272, P1473277, P1473283, P1473285, P1473289, P1473296, P1623190, P1623191, P1623192, P1623215, P1623216, Z586124, Z586125, Z586126, Z586128, Z586135, Z586137, Z586139, Z586141, Z586145, Z586146, Z586147, Z586148, Z586149, Z586150, Z586151, Z586152, Z586153, Z586154, Z586155, Z586156, Z586157, Z586158, Z586160, Z586161, Z586162, Z586163, Z586164, Z586165, Z586167, Z586168, Z586169, Z586170, Z586171, Z586172, Z586173	The magnet is intended to align and hold the coil or processing unit to a hearing implant.

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Cochlear Part (Catalogue) Number	Intended Purpose
Cochlear Magnet Reverse Polarity: P1840752, P1840753, P1840754, P1840755, P1840756, P1840757, P1840760, P715025, P715027, P715029, P715030, P715031, P715032, P715033, P715035, P715036, P715037, P715039, P715040, P715042, P715043, P715044, P715045, P715046, P715047, P715048, P715049, P715050, P715051, P715052, P715053, P715054, P715056, P715057, P715061, P715063, P715064, P715065, P715066, P715067, P715068, P715070	
Electrical and electronic accessories	
Cochlear USB Battery Charger (UC2): P1842635	The battery charger is used to charge the rechargeable battery module of the sound processor.
Cochlear Y Battery Charger (YC2): P1842636	
Cochlear Remote Control (CR310): Z569903	The remote control is intended to be used to control the normal operating functions of a processing unit as part of a hearing implant system.
Water-safe accessories	
Cochlear Aqua+: P1840596, P1840593	The Aqua+ is intended to provide improved water and dust resistance to the sound processor.
Retention Accessories	
Cochlear Earhook (EH2): P1840267, P1840269, P1840271	The retention accessory is intended to be used to assist with wearing the sound processor as part of a hearing implant system.
Cochlear Tamper Resistant Earhook (TR2): P1840434	
Cochlear Snugfit (SF2): P1840372, P1840394, P1840430	
Cochlear Hugfit (HF2): P1840351, P1840295, P1840286, P1840353, P1840355	
Cochlear Earmould Adaptor (EA2): P1840480	
Cochlear Koala Clip (KC3): P1840509	
Cochlear Headworn Adaptor: P706992, Z544861	
Cochlear BTE Headband P1335209, P1335210, P1335211, P1335212, P1335213, P1335214	

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Cochlear Part (Catalogue) Number	Intended Purpose
Adaptation accessories	
Cochlear Coil Spacer: P1191447	The coil spacer increases the spacing between the external coil and the coil of the implant.
Cochlear SoftWear pad: P793406, P793408	The SoftWear pad provides a cushioned surface to the surface of the sound processor or coil.

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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	18 Feb 2025	Added reference to Regulation (EU) 2021/2226 Re-signed following approval of SC24-09	CC
7	06 Oct 2025	Re-signed following approval of TD23-13, TD23-14 and SC24-03. Addition of the following to Declaration of Conformity: **Elements of the Nucleus 8 Sound Processor:** ▪ Cochlear™ Battery Holder ▪ Cochlear™ Battery Cover (BC3) ▪ Cochlear™ Compact Battery Module ▪ Cochlear™ Power Compact Battery Module ▪ Cochlear™ Power Extend Battery Module ▪ Cochlear™ Magnet ▪ Cochlear™ Magnet Reverse Polarity ▪ Cochlear™ Earhook (EH2) ▪ Cochlear™ Tamper Resistant Earhook (TR2) **Optional accessories of the Nucleus 8 Sound Processor:** ▪ Cochlear™ Y Battery Charger (YC2) ▪ Cochlear™ USB Battery Charger (UC2) ▪ Cochlear™ Snugfit (SF2) ▪ Cochlear™ Hugfit™ (HF2) ▪ Cochlear™ Earmould Adaptor (EA2) ▪ Cochlear™ Koala Clip (KC3) ▪ Cochlear™ Aqua+ ▪ Cochlear™ Headworn Adaptor ▪ Cochlear™ BTE Headband ▪ Cochlear™ Coil Spacer ▪ Cochlear SoftWear™ pad ▪ Cochlear™ Remote Control (CR310)	MT
8	12 Dec 2025	Editorial correction of the Basic UDI-DI for the **Cochlear™ Remote Control (Model No: CR310, P/N: Z569903)**. “321502CR310KX” replaced by "9321502CR310KX" New version 03 of the EU Certificate G70 078611 0143	MT
9	30 Jul 2026	Update reference of the QMS Certificate issued under Annex IX, Chapter I Remove Trademark symbols	MT

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Version	Date	Change	Author
10	02 Sep 2026	Update to clarify EN 300 330 v.2.1.1 only applies to N8 sound processors	SJ