Docusign Envelope ID: BD1F0370-FC10-8C9C-8009-6AC713BC24D1

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):	Kanso Sound Processor and Accessories (Refer to Schedule I for the list of applicable devices)
Intended Purpose	Kanso 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 0159 Revision: 01 Valid from: 2024-07-16 Valid until: 2028-02-09
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 v.2.3.2; EN 301 489-17 v3.2.4 **2: Effective use of spectrum allocated** − EN 300 328 v2.2.2 and 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 EU 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:
780F62E3A2F546E...

Damien Rankin

Vice President Global Quality & Regulatory

Date: 26 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
P771870	Kanso® Sound Processor	CP950	N/A	Sandy Blonde	9321502CP950SPD3	J0380	47374
P771863	Kanso® Sound Processor	CP950	N/A	Golden Blonde	9321502CP950SPD3	J0380	47374
P771875	Kanso® Sound Processor	CP950	N/A	Copper Brown	9321502CP950SPD3	J0380	47374
P771873	Kanso® Sound Processor	CP950	N/A	Chocolate Brown	9321502CP950SPD3	J0380	47374
P771862	Kanso® Sound Processor	CP950	N/A	White	9321502CP950SPD3	J0380	47374
P771872	Kanso® Sound Processor	CP950	N/A	Silver	9321502CP950SPD3	J0380	47374
P771867	Kanso® Sound Processor	CP950	N/A	Slate Grey	9321502CP950SPD3	J0380	47374
P771866	Kanso® Sound Processor	CP950	N/A	Black	9321502CP950SPD3	J0380	47374
P1473436	Kanso® Magnet	N/A	N/A	4(I)	9321502CP950MagnetXV	J0380	62944
P1473438	Kanso® Magnet	N/A	N/A	2(I)	9321502CP950MagnetXV	J0380	62944
P1473440	Kanso® Magnet	N/A	N/A	½(I)	9321502CP950MagnetXV	J0380	62944
P1473441	Kanso® Magnet	N/A	N/A	1(I)	9321502CP950MagnetXV	J0380	62944
P1473442	Kanso® Magnet	N/A	N/A	3(I)	9321502CP950MagnetXV	J0380	62944
Z502922	Kanso® Magnet	N/A	N/A	1M	9321502CP950MagnetXV	J0380	62944
Z502923	Kanso® Magnet	N/A	N/A	2M	9321502CP950MagnetXV	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
Z502924	Kanso® Magnet	N/A	N/A	3M	9321502CP950MagnetXV	J0380	62944
Z502925	Kanso® Magnet	N/A	N/A	4M	9321502CP950MagnetXV	J0380	62944
Z566412	Kanso® Magnet	N/A	N/A	½M	9321502CP950MagnetXV	J0380	62944
Z566414	Kanso® Magnet	N/A	N/A	5M	9321502CP950MagnetXV	J0380	62944
Z566415	Kanso® Magnet	N/A	N/A	6M	9321502CP950MagnetXV	J0380	62944
P737209	Kanso® Magnet Reverse Polarity	N/A	N/A	½R	9321502CP950MagnetXV	J0380	62944
P737211	Kanso® Magnet Reverse Polarity	N/A	N/A	1R	9321502CP950MagnetXV	J0380	62944
P737213	Kanso® Magnet Reverse Polarity	N/A	N/A	2R	9321502CP950MagnetXV	J0380	62944
P737214	Kanso® Magnet Reverse Polarity	N/A	N/A	3R	9321502CP950MagnetXV	J0380	62944
P737215	Kanso® Magnet Reverse Polarity	N/A	N/A	4R	9321502CP950MagnetXV	J0380	62944
P737216	Kanso® Magnet Reverse Polarity	N/A	N/A	5R	9321502CP950MagnetXV	J0380	62944
P737217	Kanso® Magnet Reverse Polarity	N/A	N/A	6R	9321502CP950MagnetXV	J0380	62944
Z594543	Cochlear™ Aqua+ for Kanso®	N/A	N/A	N/A	9321502CP950AquaPlus48	J0380	61152

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Schedule II: Intended Purposes

Cochlear Part (Catalogue) Number	Product Name	Intended Purpose
P771870, P771863, P771875, P771873, P771862, P771872, P771867, P771866	Kanso® Sound Processor	The Kanso® Sound Processor is intended to be used in combination with other devices as part of a hearing implant system to provide hearing sensation. The sound processor converts sounds into electrical signals, which it sends to an implant. The sound processor also provides power to the implant
P1473436, P1473438, P1473440, P1473441, P1473442, Z502922, Z502923, Z502924, Z502925, Z566412, Z566414, Z566415	Kanso® Magnet	The magnet is intended to align and hold the coil or processing unit to a hearing implant.
P737209, P737211, P737213, P737214, P737215, P737216, P737217	Kanso® Magnet Reverse Polarity	
Z594543	Cochlear™ Aqua+ for Kanso®	The Cochlear™ Aqua+ for Kanso® is intended to provide improved water and dust resistance to the sound processor.

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Change History

Version	Date	Change	Author
1	16-Feb-2023	Initial Introduction	Natalie Dubs
2	02-Feb-2024	Removed 'Annex III' from second bullet point on page 2.	Leigh Davey
3	31-Jul-2024	Update to include Kanso Sound Processor accessories (TD23-15 project). EU Declaration of Conformity D2119986 is abandoned and replaced by the present declaration. Update to the latest version of the template D1641136	Maxime Tirouvanziam
4	26-Aug-2026	Updated QMS Certificate to G15 0718611 0253 due to Recertification and Issuance of new Certificate. Update to Relevant standards to reflect available supporting testing: 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 v.2.3.2; EN 301 489-17 v3.2.4 2: Effective use of spectrum allocated − EN 300 328 v2.2.2 and EN 300 330 v.2.1.1	Nazira Hisham