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Dokument podpisany przez Joanna Mikołajczyk
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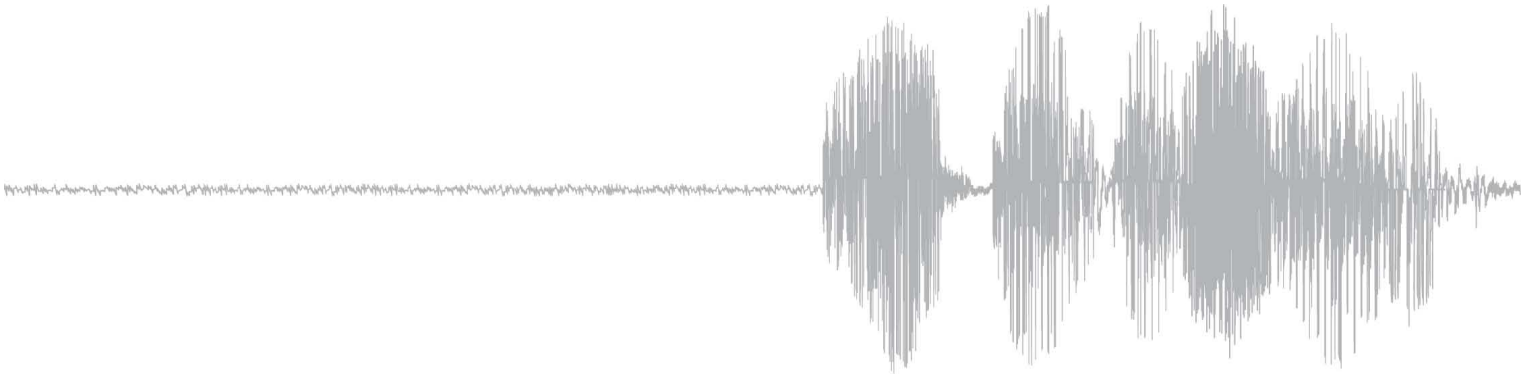

Kanso 2 Sound Processor (CP1150) EU (MDR) Declaration of Conformity

D2068714

Version: 1
State: Approved (T+B)
Approver: Steven Kennedy (skennedy)
Date : 10 Nov 2023

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Cochlear®

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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 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.
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 0183 Revision: 00 Valid from: 2023-11-09 Valid until: 2028-11-08
Common Specifications (CS):	None

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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/ A1:2013 (IEC 60601-1:2005+ AMD1:2012) **3.1 (b): Electromagnetic Compatibility –** (EN 60601-1-2 :2015/A1:2021 (IEC 60601-1-2: 2014/ AMD1:2020) **3.2: Effective use of spectrum allocated −** EN 300 328 v2.1.1

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.

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: 10 November 2023

Place: Sydney, Australia

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Schedule of Products

Cochlear Part (Catalogue) Number	Product Name	Model Number	Trade Name(s)	Option / Variant	Basic UDI-DI	GMDN code
P1320274	Kanso® 2 Sound Processor	CP1150	N/A	Sandy Blonde	9321502CP1150SP58	47374
P1320275	Kanso® 2 Sound Processor	CP1150	N/A	Silver	9321502CP1150SP58	47374
P1320276	Kanso® 2 Sound Processor	CP1150	N/A	Chocolate Brown	9321502CP1150SP58	47374
P1320277	Kanso® 2 Sound Processor	CP1150	N/A	Slate Grey	9321502CP1150SP58	47374
P1320278	Kanso® 2 Sound Processor	CP1150	N/A	Black	9321502CP1150SP58	47374

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Change History

Version	Date	Change	Author
1	Feb 2023	Initial Introduction	Behrokh Basirat Pour