Docusign Envelope ID: 59D02315-E1F6-89DB-8207-2BA42687C2D6

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):	Cochlear Part (Catalogue) Number: P1648881 Model Number: CP1150S Product Name: Cochlear™ Surgical Processor Trade Name(s) (if any): N/A Option / Variant (if any): N/A Basic UDI-DI: 9321502CP1150SSP8S GMDN Code: 64984
Intended Purpose	The Cochlear™ Surgical Processor is intended to be used in combination with other devices as part of an intraoperative measurements system during a cochlear implant surgical procedure, to convey data between a compatible cochlear implant and compatible intraoperative application software. The surgical processor converts data into electrical signals and sends the signals to the implant via a coil. The surgical processor also receives data from and 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: Certificate No.: G15 078611 0253 Revision: 00

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	Valid from: 2026-08-06 Valid until: 2031-08-05 Technical Assessment Certificate issued under Annex IX, Chapter II: Certificate No.: G70 078611 0212 Revision: 00 Valid from: 2024-01-23 Valid until: 2029-01-22
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

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.

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Authorised Signatory on behalf of Cochlear Limited and for the Person Responsible for Regulatory Compliance:

Signed by:
828A78CC59DD4EE...

Damien Rankin — Date: 11 August 2026

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

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Change History

Version	Date	Change	Author
1	23 Jan 2024	Initial Introduction (TD23-08)	CC
2	01 Feb 2024	Corrected the GMDN Code from 64985 to 64984. Corrected the Trade Name to N/A	NP
3	25 Feb 2025	Updated to latest template version. Updated RED details.	JFJ
4	Refer to WC approval record	Updated Change History details. Added reference to Regulation (EU) 2021/2226 Re-signed following approval of SC24-09	CC
5	11 Aug 2026	Updated QMS Certificate to G15 0718611 0253 due to Recertification and Issuance of new Certificate.	INCO