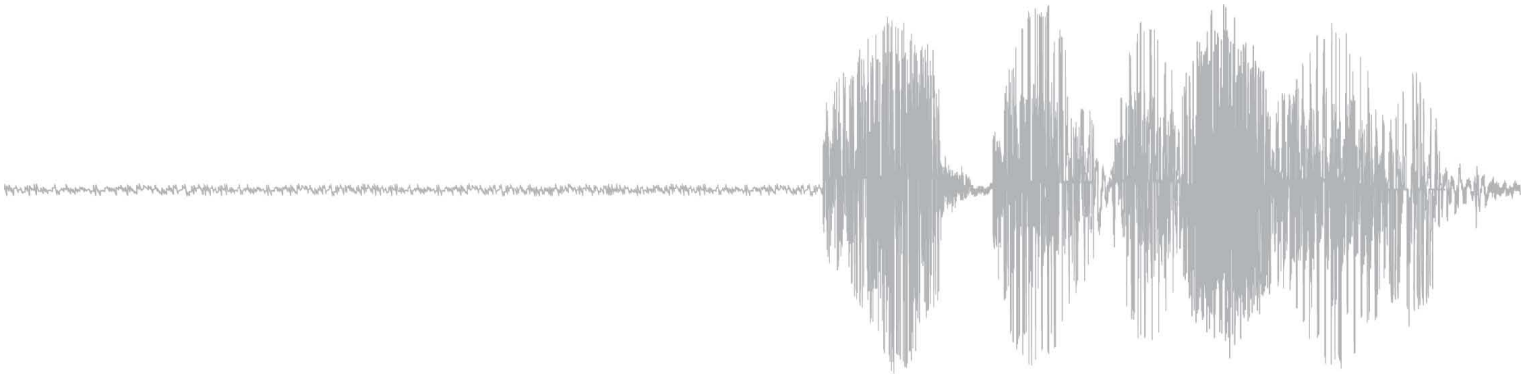

CP1110S Surgical Processing Unit EU Declaration of Conformity

D2127541

Version: 5
State: Approved (T+B)
Approver: Marcus Ignacio (MIgnacio)
Date : 07 Mar 2025

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Hear now. And always

Cochlear®

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: P1840761 Model Number: CP1110S Product Name: Cochlear™ Surgical Processing Unit Trade Name(s) (if any): N/A Option / Variant (if any): N/A Basic UDI-DI: 9321502CP1110SSP7E GMDN Code: 64984
Intended Purpose:	The surgical processing unit 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 processing unit converts data into electrical signals and sends the signals to the implant via a coil. The surgical processing unit 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 and III: Certificate No.: G12 078611 0117 Revision: 02 Valid from: 2023-01-30

	Valid until: 2026-08-05 Technical Assessment Certificate issued under Annex IX, Chapter II: Certificate No.: G70 078611 0217 Revision: 00 Valid from: 2024-02-09 Valid until: 2029-02-08
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 v3.2.5 **2: Effective use of spectrum allocated** − EN 300 328 v2.2.2; 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 of the European Parliament and of the Council of 5 April 2017 on medical devices.
- Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- 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.
- Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste 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.

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

Signed by:

828A78CC59DD4EE...

Damien Rankin — Date: 26 February 2025

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

Change History

Version	Date	Change	Author
01	12 Feb 2024	Initial Introduction (TD23-02)	CC
02	28 Feb 2024	Added declaration of conformity to the Directive 2014/53/EU requirements	CC
03	24 Jul 2024	Added references to the following EU legislation: Regulation (EC) 1907/2006 (REACH) Updated Section “Relevant Standards or other technical specifications required to be listed by regulation” in alignment with D2135338. Updated with the latest template (rev 9)	CC
04	25 Feb 2025	Updated RED details.	JFJ
05	Refer to WC approval record	Updated Change History details. Added reference to Regulation (EU) 2021/2226 Re-signed following approval of SC24-09	CC