



Nucleus 8 Processing Unit EU MDR Declaration of Conformity D1891890

Version: 1
State: Approved (T+B)
Approver: Steven Kennedy (skennedy)
Date : 26 Jul 2022

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Hear now. And always





QMS Record

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 Karl-Wiechert-Allee 76A 30625 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' |
| 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 Ridlerstraße 65, 80339 München Germany Notified Body Identification No.: 0123 |
| CE Certificate(s): | QMS Certificate issued under Annex IX, Chapter I: Certificate No.: G12 078611 0117 Revision: 01 Valid from: 2021-12-22 Valid until: 2026-08-05 Technical Assessment Certificate issued under Annex IX, Chapter II: Certificate No.: G70 078611 0143 Revision: 00 Valid from: 2022-07-21 Valid until: 2027-07-20 |
| Common Specifications (CS): | 'None' |



QMS Record

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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 + Corr.1:2010 + A11:2011 + A12:2014 (IEC 60601-1:2005 (Third Edition) + Corr.1:2006 + Corr.2:2007+A1:2012) 3.1 (b): Electromagnetic Compatibility – EN 60601-1-2:2015, (IEC 60601-1-2:2014); EN 301 489-1 v2.1.1; EN 301 489-17 v3.1.1 3.2: Effective use of spectrum allocated – EN 300 328 v2.2.2 |
|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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

Date: 22-July-2022

Vice President Global Regulatory Affairs

Place: Sydney, Australia



QMS Record

Schedule of Products

| Cochlear Part (Catalogue) Number | Product Name | Model Number | Trade Name(s) | Option / Variant | Basic UDI-DI | GMDN code |
|----------------------------------|--------------------------------------|--------------|---------------|------------------|-------------------|-----------|
| P1840233 | Cochlear™ Nucleus® 8 Processing Unit | CP1110 | N/A | Black | 9321502CP1110PU4D | 47374 |
| P1840332 | Cochlear™ Nucleus® 8 Processing Unit | CP1110 | N/A | Brown | 9321502CP1110PU4D | 47374 |
| P1840542 | Cochlear™ Nucleus® 8 Processing Unit | CP1110 | N/A | Grey | 9321502CP1110PU4D | 47374 |
| P1840403 | Cochlear™ Nucleus® 8 Processing Unit | CP1110 | N/A | Sand | 9321502CP1110PU4D | 47374 |
| P1840723 | Cochlear™ Nucleus® 8 Processing Unit | CP1110 | N/A | White | 9321502CP1110PU4D | 47374 |
| P1840111 | Cochlear™ Nucleus® 8 Processing Unit | CP1110 | N/A | Silver | 9321502CP1110PU4D | 47374 |

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Template D1641136 revision 5

Nucleus 8 Processing Unit (CP1110)

EU (MDR) Declaration of Conformity



QMS Record

Change History

| Version | Date | Change | Author |
|---------|-------------|----------------------|------------------|
| 1 | 22-Jul-2022 | Initial Introduction | Peter Montgomery |