

Declaration of Conformity

Cochlear Limited of 1 University Avenue, Macquarie University, NSW 2109, Australia, declares under our sole responsibility that the following product, to which this declaration relates, is in conformity with the listed standards:

Product name: 1. Nucleus® CP802 Processing Unit

Model number: 1. CP802

Standards:

Essential Requirements	Standards	Report #
		CP802
Health & Safety	EN 60601-1:2006 + Corr.1:2010 (IEC 60601-1:2005+Corr.1:2006+Corr.2:2007)	407307
EMC	EN 60601-1-2:2007 (IEC 60601-1-2:2007)	375946
	EN 301 489-1 v2.1.1 EN 301 489-17 v3.1.1	D1246984 D1308519
Radio	EN 300 328 v2.1.1	D1246986

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We hereby declare that all essential radio test suites have been carried out and that the above named products are in conformity to all the essential requirements of Directive 2014/53/EU.

The conformity assessment procedure referred to in Article 17 and detailed in ANNEX II of Directive 2014/53/EU has been followed. The technical documentation relevant to the above equipment is kept at our address listed above.

I declare that Cochlear Limited is exclusively responsible for this Declaration of Conformity.

Authorised Signatory:

Jlmmo Moon Sydney, Australia; 15-Nov-2018

Gemma Moore, Head of Global Regulatory Place and Date Nov/5 2018

Affairs

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