

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® CR210 Remote Control 2. Nucleus® CR220 Intraoperative Remote Assistant 3. Nucleus® CR230 Remote Assistant
Model number:	1. CR210 2. CR220 3. CR230

Standards:

Essential Requirements	Standards	Report #	
		CR210	CR220/ CR230
Health & Safety	EN 60601-1:2006 + Corr.1:2010 (IEC 60601-1:2005+Corr.1:2006+Corr.2:2007)	403950	
EMC	EN 60601-1-2:2007 (IEC 60601-1-2:2007) EN 301 489-1 v2.1.1 EN 301 489-17 v3.1.1 EN 301 489-1 v2.2.0 EN 301 489-17 v3.2.0	374591 & 398123 -- -- D1246962 D1246962	374591 & 398123 D1246960 D1246960 -- --
Radio	EN 300 328 v2.1.1	D1246963	D1246961

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:



Sydney, Australia; 03-Nov-2017

Robert Gay, Senior Regulatory Affairs Manager

Place and Date