

DECLARATION OF CONFORMITY

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

Products name:

Kanso® 2 Sound Processor

Cochlear™ Surgical Processor

Model numbers: CP1150

CP1150S

Standards:

Essential Requirements	Standards	Report #
Health &	EN 60601-1:2006+Corr.1:2010+A11:2011+A12:2014	D1669266 (CP1150)
Safety	(IEC 60601-1:2005+Corr.1:2006+Corr.2:2007+A1:2012)	D1674127 (CP1150S)
	EN62479:2010 (IEC 62479:2010)	D1668033
EMC	EN 60601-1-2:2015	D1653027
	(IEC 60601-1-2:2014)	
	EN 301 489-1 v2.1.1	D1664767
	EN 301 489-17 v3.1.1	
Radio	EN 300 328 v2.1.1	D1664747
	EN 300 330 v2.1.1	D1664768

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.

Sydney, Australia

Steven Kennedy, Global Head of Regulatory Affairs

Place and Date

17 JAN 2020.

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CP1150 Sound Processor & CP1150S Surgical Processor RED Declaration of Conformity

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