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Declaration of Conformity

Legal Manufacturer:	Cochlear Limited 1 University Avenue Macquarie University NSW 2109 Australia	
EC Representative:	Cochlear Deutschland GmbH & Co. KG Karl-Wiechert-Allee 76A 30625 Hannover Germany	
Product:	Refer to Appendix I	
GMDN Code & Term	47374 - Cochlear implant system sound processor	
Classification:	Active Implantable Medical Device (AIMD)	

I herewith declare that the products listed in Appendix I conform to the provisions of:

 The Active Implantable Medical Devices Directive 90/385/EEC Annex 1 and the conformity assessment route of Annex 2 including Part 4:

Notified Body:

TÜV SÜD Product Service GmbH

Ridlerstraße 65, 80339 München

Germany

Notified Body No:

0123

AND

 Council Directive 2014/53/EU on Radio Equipment (RED) and the conformity assessment route of Annex II.

AND

 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.

Document: D1651894

Kanso® 2 Sound Processor (Model: CP1150) Manufacturer's Declaration of Conformity Page 1 of 3

Version: 1



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

Authorised Signatory:

Steven Kennedy

Global Head of Regulatory Affairs

Date: 08 MAY 2020.

Place: Sydney, Australia

Valid to: 26May2024



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APPENDIX I

Product	Reference No.
Kanso® 2 Sound Processor - Black	P1320278
Kanso® 2 Sound Processor - Chocolate Brown	P1320276
Kanso® 2 Sound Processor - Sandy Blonde	P1320274
Kanso® 2 Sound Processor - Silver	P1320275
Kanso® 2 Sound Processor - Slate Grey	P1320277