

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:	Cochlear™ Nucleus® CI612 cochlear implant with Contour Advance® electrode (P774600), [GMDN:47373]
Classification:	Active Implantable Medical Device

I herewith declare that the above-mentioned product(s) conform(s) 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

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

Authorised Signatory:



Gemma Moore

Global Head of Regulatory Affairs

16 APRIL '19

Place: Sydney, Australia

Valid to 14/02/2024