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Zentralstelle der Länder
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bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 078611 0088 Rev. 00

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 Implant Systems
- Cochlear CI600 Series Cochlear Implants

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713147334

Valid from: 2019-02-15

Valid until: 2024-02-14

Date, 2019-02-15

Stefan Preiß



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Model(s):	see below
Facility(ies):	Cochlear Limited 1 University Avenue, Macquarie University NSW 2109, AUSTRALIA Cochlear Limited 14 Mars Road, Lane Cove NSW 2066, AUSTRALIA
Design Facility(ies):	Cochlear Limited 1 University Avenue, Macquarie University NSW 2109, AUSTRALIA
Parameters:	./.
Product:	Cochlear Implant Systems - Cochlear CI600 Series Cochlear Implants

Test Report No.: 713147334

Models:	Model no.:
Cochlear™ Nucleus® CI612 cochlear implant with Contour Advance® electrode	CI612
Cochlear™ Nucleus® CI622 cochlear implant with Slim Straight electrode	CI622
Cochlear™ Nucleus® CI632 cochlear implant with Slim Modiolar electrode	CI632
Cochlear™ Nucleus® Replacement Magnet Cassette	
Cochlear™ Nucleus® Non-Magnetic Cassette	

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