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Zentralstelle der Länder
für Gesundheitsschutz
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.:
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Cochlear™ Nucleus® CI612 cochlear implant with Contour Advance® electrode	CI612
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Cochlear™ Nucleus® CI622 cochlear implant with Slim Straight electrode	CI622
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Cochlear™ Nucleus® CI632 cochlear implant with Slim Modiolar electrode	CI632
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Cochlear™ Nucleus® Replacement Magnet Cassette

Cochlear™ Nucleus® Non-Magnetic Cassette