



Benannt durch/Designated by  
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

## 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**

**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

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