



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. 17 17 10 78611 068

**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:****External components for Cochlear Implant Systems  
- Cochlear Nucleus 7 Sound Processor**

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.:**

713109305

**Valid from:**

2017-10-23

**Valid until:**

2022-05-04

Date, 2017-10-23

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**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 17 10 78611 068****Model(s):** see attachment**Parameters:** ./.

**Facility(ies):**

Cochlear Limited  
1 University Avenue, Macquarie University NSW 2109,  
AUSTRALIA

Cochlear Limited  
14 Mars Road, Lane Cove NSW 2066, AUSTRALIA

Cochlear Limited  
12 Helen Street, Newstead QLD 4006, AUSTRALIA

**Design  
Facility(ies):**

Cochlear Limited  
1 University Avenue, Macquarie University NSW 2109,  
AUSTRALIA

Cochlear Limited  
12 Helen Street, Newstead QLD 4006, AUSTRALIA



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**Attachment for Certificate no I7 17 10 78611 068  
dated 2017-10-23**

**Products:** External components for Cochlear Implant Systems  
- Cochlear Nucleus 7 Sound Processor

Test Report No.: 713089503

**Model:**

**Model no.:**

Nucleus® 7 Processing Unit  
Cochlear™ Standard Rechargeable Battery Module  
Cochlear™ Compact Rechargeable Battery Module  
Cochlear™ Battery Cover  
Cochlear™ Battery Holder  
Cochlear™ Slimline™ Coil  
Cochlear™ Magnet  
Cochlear™ Magnet Reverse Polarity  
Cochlear™ Earhook  
Cochlear™ Tamper Resistant Earhook  
Nucleus® 7 Aqua+ Coil  
Cochlear™ Hybrid™ Earhook with Removal Tool  
Cochlear™ Hybrid™ Receiver  
Cochlear™ Hybrid™ Ear Lock  
Cochlear™ Hybrid™ Open Dome  
Cochlear™ Hybrid™ Power Dome  
Cochlear™ Hybrid™ Bass Single Dome  
Cochlear™ Hybrid™ Bass Double Dome

CP1000

Test Report No.: 713109305

**Model:**

Nucleus® 7 Sound Processor Kit

Munich, MHS-CRT, 2017-10-23

Stefan Preiß  
Certification Medical Technology