ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 078611 0123 Rev. 01

Manufacturer:

Cochlear Limited
1 University Avenue
Macquarie University NSW 2109
AUSTRALIA

Authorized Representative:

Cochlear Deutschland GmbH & Co. KG
Karl-Wiechert-Allee 76A, 30625 Hannover, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 078611 0123 Rev. 01

Report No.: 713198997

Preceding Certificate No.: G70 078611 0123 Rev. 00

Valid from: 2021-05-18
Valid until: 2026-01-21

Date of Initial Issuance: 2021-01-22

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-05-18

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G70 078611 0123 Rev. 01

Classification:	III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	9321502CP1000PU3T
Intended Purpose:	The processing unit is intended to be used in combination with other devices as part of a hearing implant system to provide hearing sensation. The processing unit converts sounds into electrical signals, which it sends, via a coil, to an implant. The processing unit also provides power to the implant. When used in combination with an audio receiver, the sound processor also delivers sound to the ear canal in recipients with residual hearing.
Device(s):	Nucleus® 7 Processing Unit, model CP1000. Available in the following variants: Nucleus® 7 Processing Unit, CP1000 - Black, Platinum Detail Nucleus® 7 Processing Unit, CP1000 - Brown Nucleus® 7 Processing Unit, CP1000 - Grey Nucleus® 7 Processing Unit, CP1000 - Sand Nucleus® 7 Processing Unit, CP1000 - Black, Golden Detail Nucleus® 7 Processing Unit, CP1000 - White
The validity of this certificate depends on conditions and/or is limited to the following:	-None-

Revision History:

Rev.	Dated	Report
00	2021-01-22	713184969

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