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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 0223 Rev. 00

Manufacturer:

Cochlear Limited
1 University Avenue
Macquarie University NSW 2109
AUSTRALIA

SRN Manufacturer - AU-MF-000009890

Authorized Representative:

Cochlear Deutschland GmbH & Co. KG
Mailänder Straße 4 a, 30539 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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 078611 0223 Rev. 00

Report No.: 713316760

Valid from: 2024-04-17
Valid until: 2029-04-16

Issue date: 2024-04-17

Christoph Dicks
Head of Certification/Notified Body

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 0223 Rev. 00

Classification:	Class III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	9321502CP1170CL
Intended Purpose:	The sound processor is intended to be used in combination with other devices as part of a hearing implant system to provide hearing sensation. The sound processor converts sounds into electrical signals, which it sends to an implant. The sound processor also provides power to the implant.
Device(s):	Cochlear™ Nucleus® Kanso® 3 Sound Processor (Model No: CP1170) available in the following variants: Black Chocolate Brown Sandy Blonde Silver Slate Grey

Classification:	Class III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	9321502CP1175CW
Intended Purpose:	The sound processor is intended to be used in combination with other devices as part of a hearing implant system to provide hearing sensation. The sound processor converts sounds into electrical signals, which it sends to an implant. The sound processor also provides power to the implant.
Device(s):	Cochlear™ Nucleus® Kanso® 3 Nexa™ Sound Processor (Model No: CP1175) available in the following variants: Black Chocolate Brown Sandy Blonde Silver Slate Grey

The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2024-04-17	713316760	Initial issuance

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