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 017853 0171 Rev. 00

Manufacturer:

MED-EL
Elektromedizinische Geräte GmbH
Fürstenweg 77A
6020 Innsbruck
AUSTRIA

SRN Manufacturer - AT-MF-000020243

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 017853 0171 Rev. 00

Report No.: 713281979

Valid from: 2024-05-23
Valid until: 2029-05-22

Issue date: 2024-05-23

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 017853 0171 Rev. 00

Classification:	Class III
Device Group:	J0380 - AUDITORY ACTIVE-IMPLANTABLE DEVICES - ACCESSORIES
Basic UDI-DI:	9008737Me17xx7N
Intended Purpose:	Audio processor for MED-EL cochlear implant and auditory brainstem implant systems, used to evoke auditory sensation.
Device(s):	SONNET 3 in variants Me1710, Me1711, Me1712, Me1713 each in colors Anthracite, Beige, Black, Ebony, White and Nordic Grey SONNET 3 EAS in variants Me1720, Me1721, Me1722, Me1723 each in colors Anthracite, Beige, Black, Ebony, White and Nordic Grey

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The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2024-05-23	713281979	Initial issuance

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