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

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 106872 0003 Rev. 01

Manufacturer:

Oticon Medical AB
Datavägen 37B
436 32 Askim
SWEDEN

SRN Manufacturer - SE-MF-000000724

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system 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 conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
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:G10 106872 0003 Rev. 01

Report No.: 713234243/ 713234246/ 713234247

Preceding Certificate No.: G10 106872 0003 Rev. 00

Valid from: 2023-05-23
Valid until: 2026-07-18

Date of Initial Issuance: 2021-07-19

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-05-23

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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(Class IIa and Class IIb Devices)

No. G10 106872 0003 Rev. 01

Classification:	Class IIa
Device Group:	Z12040282 - GENERAL MEDICINE THERAPEUTIC TREATMENT INSTRUMENTS - SOFTWARE ACCESSORIES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Y214599 - HEARING AIDS - OTHER
Intended Purpose:	-

Classification:	Class IIb
Device Group:	P020199 - OTOLOGIC PROSTHESES - OTHER
Intended Purpose:	The Bone Anchored Hearing System's intended use is for improvement of hearing for patients with conductive or mixed hearing losses, whether unilaterally or bilaterally fitted, or for those with single-sided deafness. The Implant System is intended for placement into the temporal bone to act as permanent anchorage as means to attach the sound processor and transmit the vibrations generated by the sound processor through the bones of the skull to the inner ear. In this way, the system works independent of the function of the ear canal, eardrum and middle ear.

Classification:	Class IIa
Device Group:	Q030399 - INSTRUMENTS FOR ENT SURGERY, SINGLE-USE - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	L149099 - ENT INSTRUMENTS, REUSABLE - OTHER
Intended Purpose:	-

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

Revision History:

Rev.	Dated	Report	Description
00	2021-07-19	713186502	-
01	2023-05-23	713234243/ 713234246/ 713234247	Supplemented: Other

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