



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 106872 0004 Rev. 00

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. As applicable the involvement of the notified body is limited to the aspects relating to:

- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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:G11 106872 0004 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G11_106872_0004_Rev.00)

Report No.: 713234249/ 713238341/ 713234254

Valid from: 2023-03-23

Valid until: 2028-03-22

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-03-23



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Classification: Class I
Device Group: L149099 - ENT INSTRUMENTS, REUSABLE - OTHER
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: Class I
Device Group: L149011 - ENT SURGERY DISSECTORS, REUSABLE
Device Properties: MDS 1006 - Reusable surgical instruments

Classification: Class I
Device Group: V0380 - DEVICES WITH MEASURING FUNCTIONS - ACCESSORIES
Device Properties: MDS 1006 - Reusable surgical instruments
 MDS 1010 - Devices with a measuring function

Classification: Class I
Device Group: Q030399 - INSTRUMENTS FOR ENT SURGERY, SINGLE-USE - OTHER
Device Properties: MDS 1005.2 - Sterilisation by irradiation

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

Revision History:

Rev.	Dated	Report	Description
00	2023-03-23	713234249/ 713238341/ 713234254	Initial issuance