



Certificate

No. Q5 106872 0001 Rev. 01

Holder of Certificate: **Oticon Medical AB**

Datavägen 37B
436 32 Askim
SWEDEN

Facility(ies):

Oticon Medical AB
Datavägen 37B, 436 32 Askim, SWEDEN

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design, Development, Production and Distribution of Hearing Prothesis Systems, including sterile functional bone-anchored implants, sterile and non-sterile surgical instruments and sound processors, utilizing software, and their functional accessories.

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 106872 0001 Rev. 01

Report No.: 713220236

Valid from: 2021-12-19

Valid until: 2024-12-18

Date, 2021-12-15



Christoph Dicks

Head of Certification/Notified Body