



America

CERTIFICATE

No. QS6 106872 0002 Rev. 02

Certificate Holder: Oticon Medical AB
Datavägen 37B
436 32 Askim
SWEDEN

Certification Mark:



Scope of Certificate: Design, Development, Production and Distribution of Hearing Prosthesis Systems, including Sterile Non-Active and Active Bone-Anchored Implants, Sterile and Non-Sterile Surgical Instruments and Sound Processors, utilizing Software, and their Functional Accessories

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA.
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 106872 0002 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:QS6_106872_0002_Rev.02)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F005013
Report No.: 713271142
Effective Date: 2023-03-30
Expiry Date: 2024-12-18

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Date of Issue: 2023-04-20

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: **Audit/Certification Criteria**

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820
- 21 CFR Part 821

Facility(ies):

Oticon Medical AB

Datavägen 37B, 436 32 Askim, SWEDEN

Facility Scopes:

Design, Development, Production and Distribution of Hearing Prosthesis Systems, including Sterile Non-Active and Active Bone-Anchored Implants, Sterile and Non-Sterile Surgical Instruments and Sound Processors, utilizing Software, and their Functional Accessories
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