ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 106872 0002 Rev. 01

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

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**

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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F005013**

Effective Date: **2022-01-06**

Expiry Date: **2024-12-18**

Date of Issue: 2022-01-11

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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C E R T I F I C A T E

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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. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

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 Prothesis Systems, including Sterile Functional Bone-Anchored Implants, Sterile and Non-Sterile Surgical Instruments and Sound Processors, utilizing Software, and their Functional Accessories
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