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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 066204 0020 Rev. 00

Certificate Holder: **NeilMed Pharmaceuticals, Inc.**
601 Aviation Boulevard
Santa Rosa CA 95403
USA

Certification Mark:

TÜV SÜD ISO 13485

Scope of Certificate: **Design, Development, Manufacturing, and Distribution of Salt Packets, Saline Sprays, Saline Ampoules, Sinus Sprays, Nasal Bulbs, Nasal Gels, Nasal Aspirators, Wax Removal Ear Tools, Wax Removal Ear Solution, and Neti Pots for Sinus Care, Nasal Care, Otic Care, Wound Wash, and After Piercing Care**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, USA FDA, MHLW / PMDA. 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.

DUNS No: **79-929-5915**

Effective Date: **2020-08-31**

Expiry Date: **2023-08-30**

Date of Issue: 2020-09-25

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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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

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

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

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

Facility(ies): NeilMed Pharmaceuticals, Inc.
601 Aviation Boulevard, Santa Rosa CA 95403, USA

Facility Scopes: Design, Development, Manufacturing, and Distribution of Salt Packets, Saline Sprays, Saline Ampoules, Sinus Sprays, Nasal Bulbs, Nasal Gels, Nasal Aspirators, Wax Removal Ear Tools, Wax Removal Ear Solution, and Neti Pots for Sinus Care, Nasal Care, Otic Care, Wound Wash, and After Piercing Care
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