MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD
America

C E R T I F I C A T E

No. QS6 005204 0003 Rev. 02

Certificate Holder:
ndd Medizintechnik AG
Technoparkstrasse 1
8005 Zürich
SWITZERLAND

Certification Mark:
TÜV SÜD
ISO 13485

Scope of Certificate: **Design and Development, Production, Distribution and Service of Respiratory Gas and Flow Analysis Systems and Lung Function Analyzer**

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

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, 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 005204 0003 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002408**
Report No.: **713337858**
Effective Date: **2025-01-25**
Expiry Date: **2028-01-24**

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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

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

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

Facility(ies): ndd Medizintechnik AG
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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CEPTИФИКАT ◆ CERTIFICADO ◆ CERTIFICAT