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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 024497 0031 Rev. 00

Certificate Holder: **NONIN MEDICAL, INC.**
13700 1st Avenue North
Plymouth MN 55441-5443
USA

Certification Mark:

Scope of Certificate: **Design, Development, Manufacturing, Servicing and Distribution of Oximeters, Pulse Oximeter, Cerebral Oximeters, Breathing Monitors, Non-Invasive Blood Pressure Monitors and Non-Sterile Sensors**

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

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, 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 https://www.tuev-sued.de/product-testing/certificates

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

DUNS No: **17-495-9692**

Effective Date: **2018-11-10**

Expiry Date: **2021-11-09**

Date of Issue: 2018-11-21

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

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

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

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

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

Facility(ies):

NONIN MEDICAL, INC.
13700 1st Avenue North, Plymouth MN 55441-5443, USA

Nonin Medical Inc.
13705 1st Ave., Plymouth MN 55441, USA

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