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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 044463 0031 Rev. 00

Certificate Holder: **Ergoline GmbH**
Lindenstr. 5
72475 Bitz
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Manufacturing and Distribution of Ergometers and Blood Pressure Measuring Devices, Sp02 Devices and Medical Software for Rehabilitation and Training**

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 https://www.tuev-sued.de/product-testing/certificates

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

DUNS No: **31-440-3192**

Effective Date: **2019-04-10**

Expiry Date: **2022-04-09**

Date of Issue: 2019-04-16

(Arie Henkin)
Manager, Certification Body MHS

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Regulatory Requirements: **Audit/Certification Criteria**

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

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): Ergoline GmbH
Lindenstr. 5, 72475 Bitz, GERMANY

Facility Scopes: Design and Development, Manufacturing and Distribution of Ergometers and Blood Pressure Measuring Devices, Sp02 Devices and Medical Software for Rehabilitation and Training
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