



America

CERTIFICATE

No. QS6 044463 0031 Rev. 03

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, SPO2 Devices and Medical Software for Rehabilitation and Training

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 044463 0031 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:QS6_044463_0031_Rev_03)

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

REPs Facility ID:

F002635

Report No.:

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Effective Date:

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Expiry Date:

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(Renee Walker)
Director, US Certification Body, MHS

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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):

Ergoline GmbH

Lindenstr. 5, 72475 Bitz, GERMANY

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