



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 044463 0030 Rev. 02

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

Facility(ies): **Ergoline GmbH**
Lindenstr. 5, 72475 Bitz, GERMANY

See Scope of Certificate

Certification Mark:



Scope of Certificate: **Design and development, production and distribution of ergometers and blood pressure measuring devices, SpO2 devices and medical software for rehabilitation and training**

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 044463 0030 Rev. 02

Report No.: 713343912

Valid from: 2025-02-14

Valid until: 2028-02-13

Date, 2024-12-04

Christoph Dicks
Head of Certification/Notified Body