



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
 Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class IIa, IIb or III)

No. G1 044463 0022 Rev. 01

Manufacturer: **Ergoline GmbH**
 Lindenstr. 5
 72475 Bitz
 GERMANY

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

Product Category(ies): **Ergometer, Blood Pressure Measuring
 Instruments, SpO2 Devices and Medical
 Software for Rehabilitation and Training**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713168681

Valid from: 2020-02-17

Valid until: 2024-05-26

Date, 2020-02-17

Christoph Dicks
 Head of Certification/Notified Body

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