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Zentralstelle der Länder
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bei Arzneimitteln und
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Product Service

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
 CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ 認證證書 ◆ ZERTIFIKAT

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 018915 0003 Rev. 00

Manufacturer: **ergosana GmbH**
Truchtelfinger Straße 17
72475 Bitz
GERMANY

Facility(ies): ergosana GmbH
Truchtelfinger Straße 17, 72475 Bitz, GERMANY

Product Category(ies): Ergometer

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.: 713144050

Valid from: 2019-08-16
Valid until: 2024-05-26

Date, 2019-08-14

Stefan Preiß
Head of Certification/Notified Body