REHA STIM
MEDTEC

Konformitätserklärung
Declaration of Conformity

In Übereinstimmung mit der MDR 2017/745 in Anwendung der Übergangsbestimmungen des Artikels 120 (3a)

In accordance with MDR 2017/745 in application of the transitional provisions in art. 120 (3a)

Gültig bis spätestens 31.12.2024/Valid until latest 31.12.2024

Firmenbezeichnung / Hersteller / Company name / manufacturer

Reha Stim Medtec GmbH & Co. KG,
Brunsbütteler Damm 456, D-13591 Berlin
SRN: DE-MF-000006661

Produktfamilie: Laufbänder Callis
Product family: Treadmills Callis

Produktmodelle / Product models:

Modell / Model	UDI-DI	Artikelnummer / Part no
Callis Motion Sprint 900 SE med	4260735460067	500134
Callis Motion Sprint 900 SL med	4260735460074	500133

Zweckbestimmung:
Medizinische Callis Laufbänder dienen zum definierten Training von Patienten durch Gehen oder Laufen in der Ebene oder an einer Steigung für das Gangtraining oder ein medizinisches Rehabilitationstraining.
Intended use:
Medical Callis treadmills are used for the defined walking or running training of patients on ground level or on an incline for gait training or medical rehabilitation training.

Klassifizierung / Classification

Gemäß den Klassifizierungsregeln nach Anhang IX, Regel 9 handelt es sich um Medizinprodukt der Klasse IIa.
According to the classification rules in Annex IX, rule 9, the apron is a class IIa medical device.

Hiermit erklären wir die Übereinstimmung des Medizinprodukts der Klasse IIa mit den grundlegenden Anforderungen der EU Richtlinie 93/42/EWG für Medizinprodukte (MDD) Anhang II und übernehmen die alleinige Verantwortung für die Ausstellung.

We hereby declare the compliance of the class IIa medical device with the basic requirements of the EC Directive 93/42/EEC for medical devices (MDD) Annex II and assume sole responsibility for the creation.

Die Konformitätsbewertung wurde durchgeführt nach der EU Richtlinie 93/42/EWG für Medizinprodukte (MDD) Anhang I und II
The conformity assessment was performed according to the EC Directive 93/42/EEC for medical devices (MDD) Annex I and II

Das Produkt wird mit dem CE Kennzeichnen gekennzeichnet: CE 0123
The product will be marked with the CE mark:

EG Zertifikat / EC certificate valid until: No. D1042700014
gültig bis / valid until: 26.05.2024
zusammen mit /in combination with
Bestätigung / Confirmation letter: CL 101226 0006 Rev. 00

Berlin, 26.05.2024
(Ort und Datum der Ausstellung)
(Place and date of issue)

Benannte Stelle:
TÜV Süd Product Service
Ridlerstrasse 65
D-80339 München
Kenn-Nummer 0123

Waldemar Rauch, Verantwortliche Person, PRRC
(Name und Funktion)
(name and function)

_____
(Name und Unterschrift des Befugten)
(Name and signature of authorized person)

EC-Certificate

Directive 93/42/EEC, Annex VI

Product Quality Assurance

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-207.15.04

Berlin Cert
Prüf- und Zertifizierstelle für Medizinprodukte GmbH

hereby certifies that

emotion fitness GmbH & Co. KG
Trippstadter Str.68, 67691 Hochspeyer, Germany

has implemented and uses a quality assurance system for the following scope of application:

Final checking of Medical Training Devices (see Appendix)

The audit in accordance with Annex VI of MDD 93/42/EEC (report no. B-19-065-S-RZ) provided confirmation that the requirements of Annex VI, Article 3 of MDD 93/42/EEC have been fulfilled. The Manufacturer has to be inspected periodically by the notified body according the requirements of Annex VI, Article 4 of MDD 93/42/EEC. The manufacturer is allowed to use this certification in his process for the declaration of conformity. If a product covered by this confirmation is a product of risk class IIb, an additional EC type-examination certificate according to MDD Annex III is required.

The manufacturer is allowed to place the CE-mark on the above-mentioned products in combination with the identification No. **0633**.

issued on:	**25.05.2021**
valid from:	**25.05.2021**
valid to:	**26.05.2024**

Prüf- und Zertifizierstelle Medizinprodukte GmbH BERLIN CERT AENOR Group

Dr. N. Eschweiler
Signature of authorized representative

Appendix to certificate Z-19-065-S-R VI-E-N1

from 25.05.2021

product/product category	UMDNS	Classification
motion cycle 200 med	11-592	IIa
motion cycle 600 med	11-592	IIa
motion relax 600 med	11-592	IIa
motion body 600 med	11-592	IIa
motion stair 600 med	11-592	IIa
motion cross 600 med	11-592	IIa
motion cycle 100 med	11-592	IIa
motion cycle 900 med	11-592	IIa
motion relax 900 med	11-592	IIa
motion body 900 med	11-592	IIa
motion stair 900 med	11-592	IIa
motion cross 900 med	11-592	IIa

Dr. N. Eschweiler

Signature of authorized representative

CERTIFICATE

Berlin Cert
Prüf- und Zertifizierstelle für Medizinprodukte GmbH

DAkkS Deutsche Akkreditierungsstelle D-ZM-17591-01-00

hereby certifies that

emotion fitness GmbH & Co. KG
Trippstadter Str.68, 67691 Hochspeyer, Deutschland

has implemented and uses a quality management system for the following scope of application

Production, distribution, maintenance, service and repair of medical training equipment

The audit report no. B-22-121-S-RZ provided confirmation that the requirements in the standard

DIN EN ISO 13485:2021
EN ISO 13485:2016 + AC:2018 + A11:2021
Medical devices - Quality management systems
Requirements for regulatory purposes

have been fulfilled.

Issued :	**24.10.2023**
Valid from:	**24.10.2023**
Valid until:	**10.11.2025**

Prüf- und Zertifizierstelle für Medizinprodukte BERLIN CERT AFNOR Group GmbH

Dipl.-Ing. Martin Tettke
Signature of authorised representative

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 101226 0005 Rev. 00

Manufacturer:

Reha-Stim Medtec GmbH & Co. KG
Brunsbütteler Damm 456
13591 Berlin
GERMANY

SRN Manufacturer - DE-MF-000006661

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 101226 0005 Rev. 00

Report No.: 713304505

Valid from: 2024-12-06
Valid until: 2029-12-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-12-06

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

Benannt durch/Designated by
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www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 101226 0005 Rev. 00

Classification:	Class IIa
Device Group:	Z120616 - ELECTROMECHANICAL SYSTEMS FOR PHYSICAL THERAPY
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2024-12-06	713304505	Initial issuance

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