EC-Declaration of Conformity concerning medical devices

Manufacturer: **medica Medizintechnik GmbH**
Blumenweg 8
D-88454 Hochdorf
Tel.: 07355-93 14-0
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This declaration of conformity is according to the EC-directive for medical devices 93/42/EEC – Annex II (except section 4) and in the sole sphere of responsibility of the manufacturer. The manufacturer declares that the Essential Principles in accordance to Annex I of the above named EEC-directive are fulfilled.

Classification: **IIa**

We hereby declare that the following product:

- **THERA-Trainer tigo**

Softwareversion Control and display unit 2,7“ wireless connectivity: 04.02.xx, 7”: 02.01.xx, 10,4”: 04.00.xx

and all models listed in the annex meets all requirements of the latest versions of the above named EEC-directive.

Hochdorf, 17th February 2021

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Jonathan Kopf
CEO

The conformity assessment was realised in collaboration of the notified body:
DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main – Identification number: CE0297

This EC-declaration of conformity is valid till 2024-03-02 according to the certificate Annex II of directive 93/42/EEC. (Certificate unique ID: 170770080)

Annex
„Models“ for the EC-Declaration of Conformity

Product:

- **THERA-Trainer tigo**

The products listed below are models of the product referred to in the declaration of conformity. The conformity with the regulations of the listed directive is also certified by the statement for the following products:

- **THERA-vital**
- **THERA-live**

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EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

medica Medizintechnik GmbH

Blumenweg 8
88454 Hochdorf
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Therapy motion trainer according to Annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	064866 MR2
Certificate unique ID	170770080
Effective date	2020-06-08
Expiry date	2024-03-02
Frankfurt am Main	2020-06-08

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 064866 MR2
Certificate unique ID: 170770080
Effective date: 2020-06-08

medica Medizintechnik GmbH

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Germany

Product category	Product	UMDNS-No.	Class
Therapy motion trainer	Omnicycle	11-623	IIa
	THERA-Trainer tigo	11-623	IIa
	THERA-Trainer veho	11-623	IIa
	THERA-vital	11-623	IIa
	THERA-live	11-623	IIa
	THERA-Trainer mobi	11-623	IIa
	THERA-Trainer lyra	11-623	IIa
	THERA-Trainer bemo	11-623	IIa