

# EC-Declaration of Conformity concerning medical devices

Manufacturer: **medica Medizintechnik GmbH**  
**Blumenweg 8**  
**D-88454 Hochdorf**  
Tel.: 07355-93 14-0  
Fax.: 07355-93 14-15  
E-Mail: [info@thera-trainer.de](mailto:info@thera-trainer.de)  
<http://www.thera-trainer.de>

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: **Ila**

We hereby declare that the following product:

- **THERA-Trainer tigo**

Softwareversion Control and display unit 2,7" wireless connectivity: 04.xx.00, 7": 02.01.xx, 10,4": 04.00.xx

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

Changes made to the declaration of conformity (see change history) do not affect the declared conformity of the product on 17.02.2021 (see Annex II).

Hochdorf, 13<sup>th</sup> March 2023

  
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**Dr. 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 according to the certificate Annex II of directive 93/42/EEC.  
(Certificate unique ID: 170770080)

## Change history

Version	Change description	Date
1.0	-	17.02.2021
1.1	<ul style="list-style-type: none"> <li>- Adjustment of the software version operating and display unit: 2.7" radio: 04.02 to 04.xx. The software version of the operating and display unit has only 2 digits (yy.xx), due to the software change according to "CR_DS-PH_TT-19601-2_7_ich_freeze" the 2nd digit of the version had to be adjusted. The change is a bugfix, with no changes to the functionality of the product which was evaluated as a non-significant change by the Main Chart and Chart C of MDCG 2020-3;</li> <li>- Removal of Guidance certificate validity, as it is shown on the referenced certificate.</li> </ul>	14.03.2023

# Annex I

## „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**

# Annex II

## Reference version 1.0 for the EC-Declaration of Conformity



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Hochdorf, 17<sup>th</sup> February 2021

  
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)

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