

# EC-Declaration of Conformity concerning medical devices

Manufacturer: **medica Medizintechnik GmbH**  
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**D-88454 Hochdorf**  
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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: **Ila**

We hereby declare that the following product:

- **THERA-Trainer mobi**

Softwareversion Control and display unit 2,7" wireless connectivity: 02.XX.00

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 19.06.2020 (see Annex I).

Hochdorf, 29<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	-	19.06.2020
1.1	<ul style="list-style-type: none"> <li>- Adjustment of the software version operating and display unit: 2.7" radio: 02.01 to 02.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-CL_LP_P-5372-2_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>	29.03.2023

# Annex I

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



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Classification: **Ila**

We hereby declare that the following product:

- **THERA-Trainer mobi**

Softwareversion Control and display unit mobi 2,7" wireless connectivity: 02.01.00

meets all requirements of the latest versions of the above named EEC-directive.

Hochdorf, 19<sup>th</sup> June 2020

  
**Peter 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)

#### medica Medizintechnik GmbH

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