

medica Medizintechnik GmbH
Blumenweg 8 | 88454 Hochdorf

EC-Declaration of Conformity (MDR)

Manufacturer: **medica Medizintechnik GmbH**
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Single Registration Number (SRN) : DE-MF-000005058

This declaration of conformity is according to Annex IV of the Medical Device Regulation (MDR) 2017/745 and under our sole responsibility.

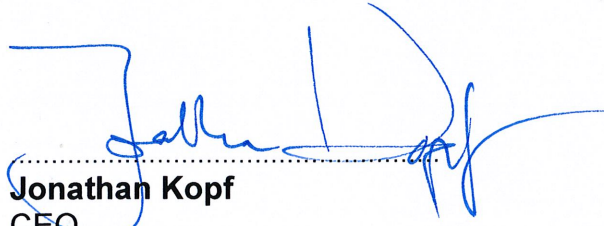
Basic UDI-DI: 4041925softGL
Product name: THERA-soft
Intended Purpose: THERA-Trainer soft is a therapy software application for feedback-controlled exercise training. In combination with a THERA-Trainer and/or a feedback sensor, movement and performance data are sent to THERA-soft via a wireless connection to provide feedback-controlled training to patients with central motor movement disorders.

Device Classification according to Annex VIII: Class I

We hereby declare that the product **THERA-soft** meets all requirements of the latest versions of MDR Regulations 2017/745 which apply to it.

Applied harmonized standards, common specifications, national standards or other normative documents are listed in document: B-01-01_DI_STR_Regulatory-reqs

Place and issue date: Hochdorf, 26th May 2021


Jonathan Kopf
CEO

This EC-Declaration of Conformity is valid until the next change of product.

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