

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: 4041925baloAX
Product name: THERA-Trainer balo
Intended Purpose: THERA-Trainer balo is a non-powered training device that provides a safe environment to train standing and balancing (postural control) and generally redevelop muscles.

Device Classification according to Annex VIII: Class I

We hereby declare that the product **THERA-Trainer balo** and all models listed in the annex meet 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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Geschäftsführer
Peter Kopf/Otto Höbel
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Models for the Declaration of Conformity

Product: **THERA-Trainer balo**

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

Product: **BALANCE-Trainer**

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