EU Declaration of Conformity

Herewith we declare under our sole responsibility that the following Class I medical device(s) (acc. Rule 1, Annex VIII) comply with the Regulation (EU) 2017/745.

Based on the conformity assessment, the declaration of conformity was issued according to Regulation (EU) 2017/745. Due to risk class 1 and according to Article 52 (7) of Regulation (EU) 2017/745 the manufacturer is entitled to conduct the conformity assessment procedure independently. An evaluation by a notified body is not required.

The implemented Quality Management System fulfills the requirements of EN ISO 13485.

M.step
M.step Kidz

Basic UDI-DI:	4026398Y0612060343
SRN of the Manufacturer:	DE-MF-000007092
Intended use:	M.step® Kidz is an ankle brace for stabilization in one plane. M.step® is an ankle brace for stabilization in one plane.
Common Specifications:	Not applicable.

We expressly state that the "registered"-sign "®" is not part of the name and is only used to identify a registered trademark, that is why it may appear at different positions.

Bayreuth, 20.06.2024

medi GmbH & Co. KG
Medicusstraße 1
95448 Bayreuth
Germany

Stefan Weihermüller, PRRC, medi GmbH & Co. KG

This declaration is valid until: 15.03.2027.