

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 Annex IV of 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 13485:2016.

medi Thumb support

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|--------------------------|---|
| Basic UDI-DI: | 4026398Y060603034K |
| SRN of the Manufacturer: | DE-MF-000007092 |
| Intended use: | medi Thumb support is a thumb brace for immobilising the saddle joint and / or metacarpophalangeal joint. |
| 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, 20.12.2023

A handwritten signature in blue ink, which appears to read 'S. Weihermüller', is written over a dotted line.

Stefan Weihermüller, PRRC medi GmbH & Co. KG



This declaration is valid until: 20.12.2026.