

# 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.

**mediven® 550 Bein / mediven® 550 leg**  
**mediven® mondi**

|                          |  |
|--------------------------|--|
| Basic UDI-DI:            | 4026398M03040501010188   |
| SRN of the Manufacturer: | DE-MF-000007092  |
| Intended use:            | Flat-knitted medical compression garment used for compression of the lower extremities, mainly for the treatment of disorders of the lymphatic system. |
| 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**



*Stefan Weihermüller, PRRC medi GmbH & Co. KG*



**This declaration is valid until: 20.12.2026.**