

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.

Spinomed® II

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|--------------------------|--|
| Basic UDI-DI: | 4026398Y060309034G |
| SRN of the Manufacturer: | DE-MF-000007092 |
| Intended use: | Spinomed® II is a brace designed to actively relieve load and correct the lumbar spine / thoracic spine in the sagittal 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, 10.01.2024



Stefan Weihermüller, PRRC medi GmbH & Co. KG



This declaration is valid until: 10.01.2027.