

# EU Declaration of Conformity

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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.

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## Genumedi® pro ROM

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|--------------------------|--|
| Basic UDI-DI:            | 4026398Y061209034J   |
| SRN of the Manufacturer: | DE-MF-000007092  |
| Intended use:            | Genumedi® pro ROM is a knee guidance orthosis with extension / flexion limitation. |
| Common Specifications:   | Not applicable.  |

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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.**