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.

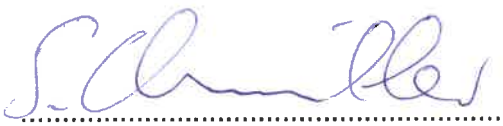
The implemented Quality Management System fulfills the requirements of EN ISO 13485:2016.

protect.Collar soft
protect.Collar soft with bar

Basic UDI-DI:	4026398Y060312033L
SRN of the Manufacturer:	DE-MF-000007092
Intended use:	protect.Collar soft is a supporter for stabilizing the cervical spine. protect.Collar soft with bar is a brace for stabilisation of the cervical spine with reinforcement.
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, 15.12.2023



Stefan Weihermüller, CEO medi GmbH & Co. KG

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This declaration is valid until: 15.12.2026.