EU Declaration of Conformity
according to Annex IV of Regulation (EU) 2017 /745 on medical devices

We, the company

Semeda GmbH
Am Petersberg 36
29389 Bad Bodenteich
Germany
SRN: DE-MF-000008334

declare in sole responsibility,

that the foot supports listed below and described and specified in the technical documentation „TD 012-01 Mittelriemenpolster Pad I“

Mittelriemenpolster, Kunststoff Pad I – Pressure Pad, plastic Pad I

Mittelriemenpolster, Kunststoff Pad I, Größe: M – Pressure Pad, plastic Pad I, Size: M; MP-2201-001

fulfils the general safety and performance requirements of

Regulation (EU) 2017 /745 on medical devices (MDR), Annex 1.

The Pressure Pad, plastic Pad I is used in combination with foot supports (or orthosis shoes), which have a pull strap or a fastening strap in the area of the back of the foot.
The Pressure Pad, plastic Pad I helps to improve the distribution of pressure on the back of the foot caused by tighten the fastening strap. In this context the Pressure Pad, plastic Pad I serves the prevention of pressure points and constrictions.

Basic-UDI-DI	426020155ZBHMRP5B
Risk class: (in accordance with MDR, Annex VIII)	**I** (Rule 1)
Performed conformity assessment procedure:	MDR, Article 52 (7)

After additions or changes to the product or to the technical documentation the declaration of conformity is reissued.

Bad Bodenteich, 30th August 2023
Place, Date

Harald Kujus
general manager

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