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 brace padding listed below and described and specified in the technical documentation „TD 011-01 BETA-Flex Schutzpolster"

BETA-Flex Schutzpolster – *BETA-Flex Brace padding*

BETA-Flex Schutzpolster – BETA-Flex Brace padding; BE 0600 - 001

fulfils the general safety and performance requirements of

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

The BETA-Flex Brace padding is used in combination with the foot abduction brace.
The foot abduction brace is used with foot supports in the system foot abduction orthosis which is used for babies/children diagnosed with idiopathic clubfoot according to the conservative therapy approach of Dr Ponseti.
The orthosis (foot supports and splint) serves to maintain the correction of the foot that has been achieved by a plaster corrective. It serves to prevent a relapse and has no corrective effect.
The BETA-Flex Brace padding acts as a soft sheathing for the foot abduction brace. Custom-fit to the splint it can be attached around it with velcro. The protective pad serves, for instance, to prevent minor injuries to children and parents (e.g. bruises), but also to protect furniture and floors from scratches.

Basic-UDI-DI	426020155ZBHSP56
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

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