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 short bar listed below and described and specified in the technical documentation
„TD 009-01 BETA-Flex Mini, kurzer Schienensteg"

BETA-Flex Mini, kurzer Schienensteg – BETA-Flex Mini, Short Bar

BETA-Flex Mini, kurzer Schienensteg – BETA-Flex Mini, Short Bar; BE 0600–002

fulfils the general safety and performance requirements of

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

The BETA-Flex Mini, Short Bar is used as an accessory for the foot abduction brace in the system foot abduction orthosis which is used for very small or premature babies diagnosed with idiopathic clubfoot according to the conservative therapy approach of Dr Ponseti.
The orthosis in which the accessory is used 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 Mini, Short Bar is used as a particularly short, lightweight middle piece in the foot abduction brace. This allows to reduce the width and weight of the splint to enable/ease therapy for particularly small patients.

Basic-UDI-DI	426020155ZBHSST6L
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.

semeda
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Bad Bodenteich, 30th August 2023
Place, Date

Harald Kujus
general manager