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 extension kit listed below and described and specified in the technical documentation „TD 008-01 ALFA-Flex XL Mitteloval, Verlängerungskit"

ALFA-Flex XL Mitteloval, Verlängerungskit – *ALFA-Flex XL Extension kit*
ALFA-Flex XL Mitteloval, Verlängerungskit – ALFA-Flex XL Extension kit; AL 0700 - 1XL

fulfils the general safety and performance requirements of

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

The ALFA-Flex XL Extension kit is used as an accessory for the foot abduction brace in the system foot abduction orthosis which is used for children 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 ALFA-Flex XL Extension kit is used as an extending middle piece in the ALFA-Flex Brace Foot Abduction Brace. This allows a higher splint width in the therapy of taller children.

Basic-UDI-DI	426020155ZBHMVSTER
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
ORTHOPÄDISCHE PRODUKTE
Am Petersberg 36 • D-29389 Bad Bodenteich • Germany
Tel.: +49-(0)5824 98 555-0 • Fax: +49-(0)5824 98 555-20

Bad Bodenteich, 30th August 2023
Place, Date

Harald Kujus
general manager