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 listed below and described and specified in the technical documentation „TD 002-02 ALFA-Flex Brace Fußabduktionsschiene/ ALFA-Flex XL Brace Fußabduktionsschiene"

ALFA-Flex Brace Fußabduktionsschienen - ALFA-Flex Brace Foot Abduction Braces

ALFA-Flex Brace Fußabduktionsschiene - ALFA-Flex Brace Foot Abduction Brace, AL 0700-000
ALFA-Flex XL Brace Fußabduktionsschiene - ALFA-Flex XL Brace Foot Abduction Brace, AL 0700-0XL

fulfils the general safety and performance requirements of

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

The ALFA-Flex Brace Foot Abduction Braces are used for babies/toddlers and children diagnosed with idiopathic clubfoot according to the conservative therapy approach of Dr Ponseti.
As one of the system components of the foot abduction orthosis it is used with foot supports.

Basic-UDI-DI	426020155FASZBSXV
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, 22nd March 2022
Place, Date

Beate Wichers
general manager

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