

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



We, the company

Semededa 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 001-02 ALFA-Flex Schuhe/Fußhalterungen“

ALFA-Flex Schuhe/Fußhalterungen – ALFA-Flex Shoes/ Foot Supports

***ALFA-Flex Schuhe/ Fußhalterungen Henry – ALFA-Flex Shoes/ Foot Supports Henry,
AL 1411-size-side***

fulfils the general safety and performance requirements of

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

The ALFA-Flex Shoes/ Foot Supports Henry 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 one of the foot-abduction braces.

Basic-UDI-DI 426020155FHSCHX8

Risk class: I
(in accordance with MDR, Annex VIII) (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

  **semededa**
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