

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



We, the company

**Sameda 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 004-02 COMFOOT Bandagenschuhe/Fußhalterungen“

**COMFOOT Bandagenschuhe/Fußhalterungen – COMFOOT Bandage Shoes/ Foot Supports**

- COMFOOT-Blue Bandagenschuhe/ Fußhalterungen*
- COMFOOT-Blue Bandage Shoes/ Foot Supports, CB 1811-size-side*
- COMFOOT-White Bandagenschuhe/ Fußhalterungen*
- COMFOOT-White Bandage Shoes/ Foot Supports, CW 1833-size-side*

fulfils the general safety and performance requirements of

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

The COMFOOT Bandage Shoes/ Foot Supports 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** 426020155FHSCX8

**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, 22<sup>nd</sup> March 2022  
Place, Date

Beate Wichers  
general manager



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