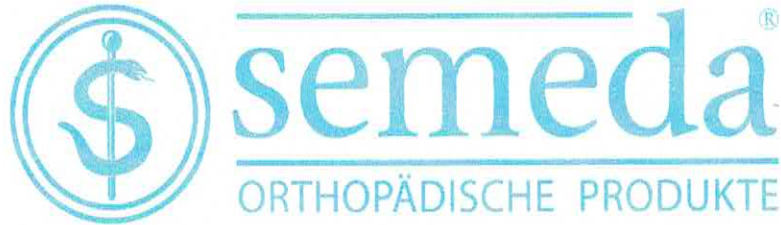


EU Declaration of Conformity
according to Annex IV of Regulation (EU) 2017 /745 on medical devices



We, the company

Semeda GmbH
Am Petersberg 36
29389 Bad Bodenteich
Germany
SRN: DE-MF-000008334
declare in sole responsibility,

that the heel pad listed below and described and specified in the technical documentation
„TD 005-02 ALFA-Soft Fersenpolster“

ALFA-Soft Fersenpolster, ALFA-Soft Heel Pad
ALFA-Soft Fersenpolster klein – ALFA-Soft Heel Pad small, AL 1700-001
ALFA-Soft Fersenpolster groß - ALFA-Soft Heel Pad large, AL 1700-002

fulfils the general safety and performance requirements of

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

The ALFA-Soft Heel Pad is a heel pad as accessories for the product ALFA-Flex Schuhe/Fußhalterungen – ALFA-Flex Shoes/ Foot Supports. These products are used in the conservative therapy of diagnosed idiopathic clubfoot. The heel pad can be attached to the shoe and prevents or reduces pressure points.

Basic-UDI-DI	426020155ZBHFP3X
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



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Beate Wichers
general manager