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

semeda®
ORTHOPÄDISCHE PRODUKTE

We, the company

Semeda GmbH
Am Petersberg 36
29389 Bad Bodenteich
Germany
SRN: DE-MF-000008334

declare in sole responsibility,

that the sole plates listed below and described and specified in the technical documentation „TD 006-02 ALFA-Flex Sohlenplatten"

ALFA-Flex Sohlenplatten – ALFA-Flex Sole Plates
ALFA-Flex Sohlenplatten – ALFA-Flex Sole Plates ET 0700-003

fulfils the general safety and performance requirements of

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

The ALFA-Flex Sole Plates are accessories for the foot abduction braces:
ALFA-Flex Brace Fußabduktionsschiene- ALFA-Flex Brace Foot Abduction Brace, ALFA-Flex XL Brace Fußabduktionsschiene - ALFA-Flex XL Brace Foot Abduction Brace, BETA-Flex Brace Fußabduktionsschiene- BETA-Flex Brace Foot Abduction Brace and ECO-Brace Light Fußabduktionsschiene- ECO-Brace Light Foot Abduction Brace.
These products are used in the conservative therapy of diagnosed idiopathic clubfoot.
The ALFA-Flex Sole Plates are used to attach external custom-made foot supports to one of these foot abduction braces.

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

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

Beate Wichers
general manager