

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 brace padding listed below and described and specified in the technical documentation
„TD 010-01 ALFA-Flex Schutzpolster“

ALFA-Flex Schutzpolster – ALFA-Flex Brace padding
ALFA-Flex Schutzpolster – ALFA-Flex Brace padding; AL 0700 - 001

fulfils the general safety and performance requirements of

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

The ALFA-Flex Brace padding is used in combination with the foot abduction brace.

The foot abduction brace is used with foot supports in the system foot abduction orthosis which is used for babies/children diagnosed with idiopathic clubfoot according to the conservative therapy approach of Dr Ponseti.

The orthosis (foot supports and splint) serves to maintain the correction of the foot that has been achieved by a plaster corrective. It serves to prevent a relapse and has no corrective effect.

The ALFA-Flex Brace padding acts as a soft sheathing for the foot abduction brace. Custom-fit to the central oval it can be attached around it with velcro. The protective pad serves, for instance, to prevent minor injuries to children and parents (e.g. bruises), but also to protect furniture and floors from scratches.

Basic-UDI-DI 426020155ZBHSP56

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, 30th August 2023

Place, Date

sameda
ORTHOPÄDISCHE PRODUKTE
Am Petersberg 36 • D-29389 Bad Bodenteich • Germany
Tel.: +49-(0)5824 98 555-0 • Fax.: +49-(0)5824 98 555-20

Harald Kujus
general manager