

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 listed below and described and specified in the technical documentation
„TD 007-02 ECO-Brace Light Fußabduktionsschiene“

ECO-Brace Light Fußabduktionsschienen – ECO-Brace Light Foot Abduction Braces
ECO-Brace Light Fußabduktionsschiene – ECO-Brace Light Foot Abduction Brace, EC 0500-002

fulfils the general safety and performance requirements of

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

The ECO-Brace Light Foot Abduction Brace is 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 foot supports.

Basic-UDI-DI 426020155FASZBSXV

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

sameda
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