

EC Declaration of Conformity EU-Konformitätserklärung

Dok-Nr.: 01845DOC Version 01

**We – SPORLASTIC GmbH | SRN | Weberstraße 1 | D-72622 Nürtingen –
being the manufacturer of**

Productgroup 4 Fussbandage

consisting of
(products are listed in Annex)

declare under our sole responsibility that the products

conform to the requirements of Medical Device Regulation (EU) 2017/745, other relevant Union legislation and amendments and meet the relevant General Safety and Performance Requirements of Annex I.

All devices are designed, manufactured, tested and released for sale in accordance with the Technical Documentation, the applicable standards and common specifications (CS).

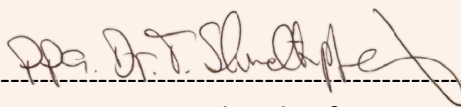
The conformity assessment procedure was done following Annex IV (V) of Medical Device Regulation (EU) 2017/745

Device Classification according to Annex VIII:
Produktklassifizierung nach Anhang VIII:

Class I
Klasse I

The list of applied standards and common specifications is part of the Technical Documentation and can be looked up upon request.

SPORLASTIC GmbH | Weberstraße 1 | D-72622 Nürtingen meets the requirements of Medical Device Regulation (EU) 2017/745 Art. 10 and maintains a certified quality management system that complies with the Medical Device Regulation and EN ISO 13485.



Dr. Timo Schmeltzpfenning
Leiter der Entwicklung, Prokurist
SPORLASTIC GmbH

<u>Nürtingen, 72622, Germany</u> Place
<u>26.05.2021</u> date of issue
<u>27.06.2024</u> valid until
approved and released stamp SPORLASTIC

ANNEX

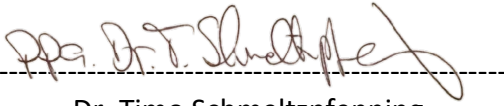
Product.No.	Produktname / Beschreibung Product Name / Description	Klasse Class	Basis UDI DI	Regel Rule	CND Code
07905	Metarso	I	4029925-Y061203-UR	1	Y061203

Zweckbestimmung Produktgruppe 4 Fussbandage:
 Fussbandagen dieser Art umschließen den Vorfuß zirkulär und sind vorzugsweise aus einem elastischen
 Gestrick gefertigt. Eine variable positionierbare Spreizfußpelotte hat die Aufgabe die
 Metatarsalköpfchen zu entlasten. Das Produkt ist über einen Verschluss einstellbar.

Produkte dieser Art werden bei Schmerzen im Bereich der Mittelfußköpfchen, bei Metatarsalgien und
 bei Spreizfüßen eingesetzt.

PMS activities are planned, executed, followed up and documented for all products in scope of this
 declaration of conformity according Medical Device Regulation (EU) 2017/745, Annex III.

Document Version	Change Note / Description
01	Initial version



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