EC Declaration of Conformity

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EU-Konformitätserklärung

Dok-Nr.: 03561DOC Version 01

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

Productgroup 29 Handgelenkbandage

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:	**Class I**
Produktklassifizierung nach Anhang VIII:	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 I Weberstraße 1 I 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

Nürtingen, 72622, Germany
Place

26.05.2021
date of issue

27.06.2024
valid until
approved and released stamp SPORLASTIC

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ANNEX

Product.No.	Produktname / Beschreibung Product Name / Description	Klasse Class	Basis UDI DI	Regel Rule	CND Code
07057	Manudyn	I	4029925-Y060612-V7	1	Y060612
07037	Manudyn Basic	I	4029925-Y060612-V7	1	Y060612
07157	Manudyn Supreme	I	4029925-Y060612-V7	1	Y060612
07657	Manudyn Pollex	I	4029925-Y060613-V9	1	Y060613
07207	Handgelenkstütze	I	4029925-Y060612-V7	1	Y060612
07033	Handgelenkstütze	I	4029925-Y060612-V7	1	Y060612

Zweckbestimmung Produktgruppe 29 Handgelenkbandage:
Bandagen dieser Produktgruppe sind Handgelenk-Kompressionsbandagen aus elastischem Zweizugmaterial, die Handgelenk, Mittelhand und einen Teil des Unterarms umschließen. Durch eine Verstärkung bzw. Pelotte wird das Handgelenk gestützt. Die Bandagen sind meist zirkulär geschlossen oder haben ggf. einen regulierbaren Verschluss.
Bandagen dieser Produktgruppe werden eingesetzt, bei Schädigung des Handgelenkes mit Belastungs-/Bewegungsschmerzen (als Verletzungsfolge, nach Operation, bei Degeneration).

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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