

**EC Declaration of Conformity**  
**EU-Konformitätserklärung**

Dok-Nr.: 02802DOC Version 01

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

**Productgroup 21 Thoraxbandage**

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).

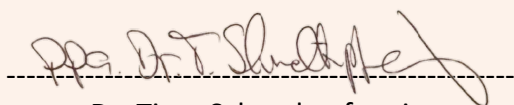
**The conformity assessment procedure was done following Annex IV (V) of  
Medical Device Regulation (EU) 2017/745**

**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

*Nürtingen, 72622, Germany*  
Place  

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26.05.2021  
date of issue  

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27.06.2024  
valid until  
approved and released stamp SPORLASTIC

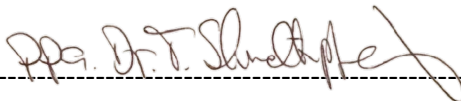
## ANNEX

Product.No.	Produktname / Beschreibung Product Name / Description	Klasse Class	Basis UDI DI	Regel Rule	CND Code
07028	Rippengürtel für Männer	I	4029925-Y060399-VW	1	Y060399
07029	Rippengürtel für Frauen	I	4029925-Y060399-VW	1	Y060399
07039	Stuttgarter Brustgürtel	I	4029925-Y060399-VW	1	Y060399

Zweckbestimmung Produktgruppe 21 Thoraxbandage:  
 Bandagen dieser Produktgruppe sind thoraxumfassende Gürtel aus elastischen Textilien. Die Kompressionswirkung lässt sich mittels Verschlüssen dosieren. Diese Bandagen dienen zur Ruhigstellung und Kompression des Thorax. Eingesetzt werden Bandagen dieser Art bei Schädigung der Rippen, als Verletzungsfolge; Fraktur, erheblich ausgeprägter Kontusion mit Atmungs-/Bewegungsschmerzen.

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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