

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

Dok-Nr.: 03561DOC Version 01

**We – SPORLASTIC GmbH | SRN | Weberstraße 1 | 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).

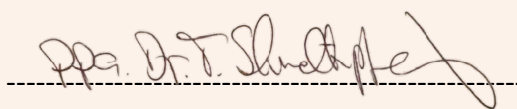
**The conformity assessment procedure was done following Annex IV (V) of  
Medical Device Regulation (EU) 2017/745**

**Device Classification according to Annex VIII:**  
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

