

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

Dok-Nr.: 04254DOC Version 01

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

**Productgroup 34 Daumenorthese**

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).

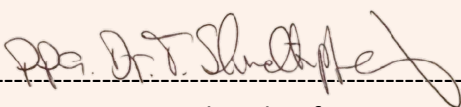
**The conformity assessment procedure was done following Annex IV (V) of Medical Device Regulation (EU) 2017/745**

**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

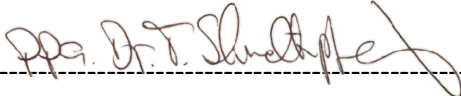
## ANNEX

Product.No.	Produktname / Beschreibung Product Name / Description	Klasse Class	Basis UDI DI	Regel Rule	CND Code
07610	Rhizo Hit	I	4029925-Y060613-V9	1	Y060613
07605	Rhizo Hit Classic	I	4029925-Y060613-V9	1	Y060613
07630	Rhizo Hit Basic	I	4029925-Y060613-V9	1	Y060613
07151	Mittelhanddaumen- schiene	I	4029925-Y060613-V9	1	Y060613
07212	Rhizosplint	I	4029925-Y060613-V9	1	Y060613
07601	Rhizo Ring	I	4029925-Y060613-V9	1	Y060613
07603	Rhizo Ring soft	I	4029925-Y060613-V9	1	Y060613

Zweckbestimmung Produktgruppe 34 Daumenorthese:  
 Daumenorthesen dieser Art dienen zur Stabilisierung und/oder Immobilisierung des Daumensattel-  
 und/oder Grundgelenks und bestehen z. B. aus thermoplastischem Kunststoff mit regulierbaren  
 Verschlusssystemen. Hauptindikationen sind Rhizarthrosen des Daumensattelgelenks und Verletzungen,  
 Bandinstabilitäten im Bereich des Daumengrund- und Daumensattelgelenks (z.B. Skidaumen).

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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