EC Declaration of Conformity

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EU-Konformitätserklärung

Dok-Nr.: 04254DOC Version 01

We – SPORLASTIC GmbH I SRN I Weberstraße 1 I 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:	**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
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

ppa. Dr. T. Schmeltzpfenning

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