EC Declaration of Conformity

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EU-Konformitätserklärung

Dok-Nr.: 00096DOC Version 01

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

Productgroup 9 Kniebandagen

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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SPORLASTIC ORTHOPAEDICS

ANNEX

Product.No.	Produktname / Beschreibung Product Name / Description	Klasse Class	Basis UDI DI	Regel Rule	CND Code
07181	Genu Hit Supreme	I	4029925-Y061209-V5	1	Y061209
07081	Genu Hit	I	4029925-Y061209-V5	1	Y061209
07086	Genu Hit Basic	I	4029925-Y061209-V5	1	Y061209
07083	Genu Hit +	I	4029925-Y061209-V5	1	Y061209
07087	Genu Hit + Comfort	I	4029925-Y061209-V5	1	Y061209
07088	Genu Hit RS	I	4029925-Y061209-V5	1	Y061209
07089	Genu Hit Wing	I	4029925-Y061209-V5	1	Y061209
07085	Patelladyn	I	4029925-Y061209-V5	1	Y061209
07097	Super- Genuplus	I	4029925-Y061209-V5	1	Y061209
07730	Meniskus-Kniebandage	I	4029925-Y061209-V5	1	Y061209
87081	Genu Hit Kids	I	4029925-Y061209-V5	1	Y061209
07084	Kniebandage bei Morbus-Schlatter	I	4029925-Y061209-V5	1	Y061209

Zweckbestimmung Produktgruppe 9 Kniebandage:
Kniebandagen zur Weichteilkompression sind Kompressionsbandagen mit lokaler/lokalen Druckpelotte(n) aus flexiblem Material um die Kniescheibe. Die Produkte werden zur Weichteilkompression/elastischen Stützung und Druckentlastung an Band-/Faszienansätzen am Knie eingesetzt. Die Zielgruppe zeigt Beeinträchtigungen des Gehens/Stehens bei Schädigung des Kniegelenkes (als Verletzungsfolge, nach Operation, bei Degeneration).
Alle Produkte dieser Produktgruppe zeichnen sich durch eine definierte Kompression aus und verwenden Pelotten zur Druckentlastung und Stabilisierung.

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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