EC Declaration of Conformity

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EU-Konformitätserklärung

Dok-Nr.: 01977DOC Version 01

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

Productgroup 12 Knieorthesen OA

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
07750	V-Force	I	4029925-Y061209-V5	1	Y061209
07788	Genudyn OA mediale Ausführung	I	4029925-Y061209-V5	1	Y061209
07789	Genudyn OA Laterale Ausführung	I	4029925-Y061209-V5	1	Y061209
07790	Kneo - mediale Ausführung	I	4029925-Y061209-V5	1	Y061209
07791	Kneo - laterale Ausführung	I	4029925-Y061209-V5	1	Y061209
07792	Kneo - mediale Ausführung, Sondergrößen	I	4029925-Y061209-V5	1	Y061209
07793	Kneo - laterale Ausführung, Sondergrößen	I	4029925-Y061209-V5	1	Y061209

Zweckbestimmung Produktgruppe 12 Knieorthesen OA:
Orthesen dieser Produktgruppe verfügen über eine selbsttragender Rahmenkonstruktion und dienen zur Entlastung eines Kompartiments nach dem 3-Punkt-Prinzip und können zum zur physiologischen Führung und Stabilisierung nach dem 4-Punkt-Prinzip des Kniegelenks dienen.
Orthesen dieser Gruppe werden eingesetzt bei allen Indikationen und Beschwerden, bei denen eine unikompartimentelle Belastungsreduktion erforderlich ist, wie z.B. eine Gonarthrose.

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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