

EC Declaration of Conformity
EU-Konformitätserklärung

Dok-Nr.: 03495DOC Version 01

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

Productgroup 28 Ellenbogenorthese

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).

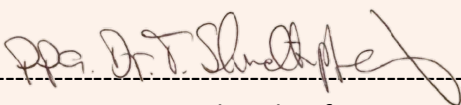
**The conformity assessment procedure was done following Annex IV (V) of
Medical Device Regulation (EU) 2017/745**

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
26.05.2021
date of issue
27.06.2024
valid until
approved and released stamp SPORLASTIC

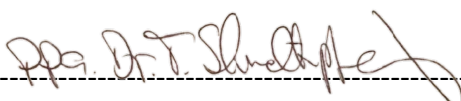
ANNEX

Product.No.	Produktname / Beschreibung Product Name / Description	Klasse Class	Basis UDI DI	Regel Rule	CND Code
07560	SP Elbow Hand Brace	I	4029925-Y060619-VM	1	Y060619
07520	ROM Ellbogenorthese	I	4029925-Y060630-V9	1	Y060630

Zweckbestimmung Produktgruppe 28 Ellenbogenorthese:
 Orthesen dieser Produktgruppe dienen zur Mobilisierung des Ellenbogengelenks in einstellbaren Bewegungsumfängen mit Immobilisierung des proximalen Radius-Ulnar-Gelenks mittels einstellbarer Fixierung im Handgelenk.
 Orthesen dieser Produktgruppe können alle Indikationen versorgen, bei denen eine frühfunktionelle Mobilisierung mit Bewegungsbegrenzung des Ellenbogengelenks und Immobilisierung des proximalen Radius-Ulnar-Gelenks notwendig ist.

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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