EC Declaration of Conformity

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EU-Konformitätserklärung

Dok-Nr.: 02439DOC Version 01

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

Productgroup 19 Skoliose

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
07310	TriaC II	I	4029925-Y060309-V3	1	Y060309

Zweckbestimmung Produktgruppe 19 Skoliose:
Orthesen dieser Produktgruppe sind dynamische Skoliose-Orthese in einer offenen Rahmenkonstruktion. Der selbsttragende Rahmen wird durch unelastische und teilelastische Gurte sowie durch Kunststoffpelotten ergänzt und zirkulär am Thorax und der Hüfte getragen.
Orthesen dieser Produktgruppe können zur Versorgung von idiopathischen Skoliosen bis 35 Grad nach Cobb eingesetzt werden.

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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