EC Declaration of Conformity

EC Declaration of Conformity
EU-Konformitätserklärung

Dok-Nr.: 02208DOC Version 01

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

Productgroup 8 Silikoneinlagen

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

EC Declaration of Conformity

SPORLASTIC ORTHOPAEDICS

ANNEX

Product.No.	Produktname / Beschreibung Product Name / Description	Klasse Class	Basis UDI DI	Regel Rule	CND Code
07910	Calcalastic	I	4029925-Y061203-UR	1	Y061203
07915	Calcalastic long	I	4029925-Y061203-UR	1	Y061203

Zweckbestimmung Produktgruppe 8 Silikoneinlagen:
Produkte dieser Gruppe sind viscoelastische Fersenkissen, bestehend aus Silikon und werden auch als Stoßabsorber bezeichnet. Integrierte Softspots befinden sich im Bereich der Ferse und / oder den Metatarsalköpfchen. Stoßabsorber dienen dazu, lokale Beschwerden des Fersenauftrittsbereichs durch Spitzenstoßbelastungen abzufangen. Mögliche Indikationen sind zum Beispiel Fersensporn, nach zementloser Endoprothesenversorgung sowie bei verschiedenen arthrotischen Erkankungen (z.B. Knie, Sprunggelenk)

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

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