



Uniprox GmbH & Co. KG _ Heinrich-Heine-Straße 4 _ 07937 Zeulenroda-Triebes

Zeulenroda-Triebes, 27.04.2026

EU Declaration of Conformity

We,

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declare in exclusive accountability that our products meet the general safety and performance requirements according to Annex I of the European Medical Device Regulation 2017/745 of the European Parliament and of the Council (MDR) and that, after the conformity assessment procedure according to Article 52 (7), they comply with the relevant provisions of the MDR.

A notified body is not involved in the conformity assessment procedure.

Description/ Order No.	Intended Purpose	GMDN	Basic-UDI-DI
Prosthetic Feet F90 F310 Chopart F340 Mid-Profile	Prosthetic feet are the base structure of a lower limb prosthesis.	64723	4053646Feet7N
Adapter A1-Al, A1-St, A1-Ti, A1-St34, A2-Ti, A3-Al200, A3-Al400, A3-St200, A3-St400, A3-Ti200, A3-Ti400, A4-St200, A4-St400, A4-Ti400, A6-Al, A6-St, A6-Ti, A8-Ti, A9-Ti, A10-Al, A10-St, A10-Ti, A11-St, A11-Ti, A13, A13-Al, A13-St, A13-Ti, A14-St, A14-Ti, A15-St, A17-St, A18-St, A19-St, A20-St, A21-St, A22-St, A22-Ti,	Adapters are load-bearing components within a prosthesis.	61229	4053646AdapterP7

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<p>A23-St, A23-Ti, A25-Ti, A26-AL, A27-AL1, A27-AL2, A27-AL3, A28-AL, A29-AL, A30, A37-Ti1, A37-Ti2, A37-Ti3, A37-Ti4, A38-St, A39-Ti, A40-Ti1, A41-Ti1, A41-Ti2, A49-Ti1, A49-Ti2, A60-148, A60-120, A60-30, A86, A87, E-F01, E-F02, E-F04, R1-AL400, TA-1, TA2, VA1-Ti, VA2-Ti, VA9-AL</p>			
<p>Knee Joint JT01 JT02-St, JT02-Ti JT03 JT05-St, JT05-Ti JT09 JT20-M36, JT20-PYR, JT20S-M36, JT20S-PYR, JT22-M36, JT22-PYR, JT22S-M36, JT22S-PYR</p>	<p>Knee joints are used as the articulated connection between a transfemoral socket and the modular structure of the lower limb prosthesis.</p>	<p>64718 (JT01, JT02-St, JT02-Ti, JT03, JT05-St, JT05-Ti, JT09) 64719 (JT20-M36, JT20-PYR, JT20S-M36, JT20S-PYR, JT22-M36, JT22-PYR, JT22S-M36, JT22S-PYR)</p>	<p>4053646Knee98</p>
<p>Stump care Silicone Liner and -products L03-[size], L20-[size] L01-[size] L14-1, L14-2, L15-1, L15-2 SoftskinAir®-Liner S-2L-Air, S30-Air, S30CL-Air, S40-Air, S40CL-Air, S50-Air, S50CL-Air, SC30-Air, SC40-Air, Sport-Air,</p>	<p>Liners and Silicone products are removable linings between the residual limb and the socket. The nylon compression sheaths serve as an intermediate layer between the residual limb and the socket and protect the skin from irritation when wearing a leg prosthesis.</p>	<p>41536</p>	<p>4053646StumpHR</p>



STF-Air, STF-2L-Air Softskin-Liner S-2L, S30, S30CL, S40, S40CL, S50, S50CL, SC30, SC40, STF, STF-2L Nylon Compression Sheaths ST80, ST81, ST82			
Socket Fixation VJ1, VJ2, V08, V09, V09-A, V10, V10-A, V13, V18, V20, V21, V22, ShL1, ShL20, ShL3A-2, ShL40A, ShL40B ShL5B, ShL50B, ShL6A EM	Socket fixations are used to securely connect the residual limb in the socket of a leg prosthesis.	64715	4053646SocketFixGT
Torsion Orthosis/ Pelvic Band OB100, OB101, OB102	The torsion splint is a leg orthosis for the dynamic correction of rotational pathologies of the lower leg and foot.	66056	4053646TorsionBB
DAHO®- Orthosis Typ 1, Typ 2.1 – 2.4, Typ 2.6, Typ 2.D Typ 3, Typ 3.1 Typ 4, Typ 4P	Hand orthoses are used for immobilization, mobilization and/or correction.	41457	4053646DAH0W2

Our products have been classified in **risk class I** in accordance with Annex VIII, chapter III of the Regulation (EU) 2017/745 of the European Parliament and of the Council and comply with the relevant provisions.

Steffen Lasch
 Person Responsible for Regulatory Compliance

Ingo Schneider
 Managing Director

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 uniprox®



Version history:

<i>Version</i>	<i>Effective Date</i>	<i>Reason for Revision</i>
000	25. May 2021	New Document
001	01.10.2021	Addition SRN; SoftskinAir Duo/ Softskin Duo added
002	12.01.2023	Change from S-Duo-Air/ S-Duo to S-2L-Air/ S-2L
003	09.10.2023	SC30-Air and SC30 added
004	25.03.2024	ShL6A added
005	26.04.2024	Re-Grouping BASIS-UDI-DI; Changing Intended Use
006	17.05.2024	Adding the new Softskin/ -Air® Liner STF-2l and STF-2L-Air
007	10.06.2024	Adjusting the intended use of the torsion orthosis
008	12.11.2024	Addition of the GMDN code
009	29.01.2025	F310 Chopart added
010	03.04.2025	Corrective regulatory reference; change of the Basic-UDI-DI for the product group "silicone liners and products"
011	16.09.2025	Addition of nylon compression sheaths and change of basic UDI-DI for stump care
012	27.04.2026	F340 Mid-Profile added