



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

Zeulenroda-Triebes, October 09th 2023

EU Declaration of Conformity

(according to Annex IX Regulation (EU) 2017/745 of the European Parliament and of the Council)

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We,

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declare in exclusive accountability that our products meet the general safety and performance requirements set out in Annex I of the European Medical Device Regulation 2017/745.
A notified body is not involved in the conformity assessment.

Description/ Order No.	Intended Purpose	Basic-UDI-DI
Uniprox Multiaxial carbon fiber foot F90-[size]-[side]	The F90 Uniprox Multiaxial Carbon Foot is the basis of the modular leg prosthesis.	4053646F9083
Socket Adapter A10-Al, A10-St, A10-Ti, A11-St, A11-Ti, A13-Al, A13-St, A13-Ti, A13, A14-St, A14-Ti	4-Hole Adapters are the connection between a pyramid attachment or a pyramid receiver and 4-hole threat adapter to a modular prosthetic limb prosthesis.	40536464LochAd5E
Double Adapter A37-Ti1, A37-Ti2, A37-Ti3, A37-Ti4, A38-St, A39-Ti, A41-Ti1, A41-Ti2 Multipurpose Joint Adapter A49-Ti1, A49-Ti2	Double adapters are the connection between two adapters in a modular prosthetic limb prosthesis.	4053646DoppelAdHP
Rotation Adapter TA-1, TA2	The rotation adapters are fit between the prosthetic knee and AK-Socket for rotation purpose of the lower part of the modular prosthetic limb prosthesis.	4053646DrehAdCK
Socket Adapter A6-Al, A6-St, A6-Ti, A8-Ti, A9-Ti, A15-St, A17-St, A18-St, A19-St, A20-St, A21-St Knee disarticulation Adapter A86	The lamination anchors are for usage in a modular prosthetic limb prosthesis und laminated into the prosthetic socket.	4053646EingussXD
Attachment Plate A26-Al, A27-Al1, A27-Al2, A27-Al3 Lamination Attachment Plate A28-Al, A29-Al	The lamination attachment plates are for usage in a modular prosthetic limb prosthesis und laminated into the prosthetic socket.	4053646EingussscheibeC5



Foot Adapter E-F01, E-F02, E-F04	The modular adapters E-F01, -02 and -04 are the connection to the Sach feet F1 and F20.	4053646FussAdK7
Socket Attachment Block A60-148, A60-120, A60	The wooden socket attachment blocks are for usage in a modular prosthetic limb prosthesis und laminated into the prosthetic socket.	4053646HolzansatzXM
Tube Adapter A3-Al200, A3-Al400, A3-St200, A3-St400, A3-Ti200, A3-Ti400, A4-St200, A4-St400, A4-Ti400 Pylon R1-Al400	The tube adapters connect pyramid adapters to adapters with tube clamps in a modular prosthetic limb prosthesis.	4053646RohrAdKF
...		
Tube Clamp Adapter A1-Al, A1-St, A1-Ti, A1-St34, A2-Ti, A40-Ti1 Reduction Adapter A30	The tube clamp adapters connect pyramid adapters or pyramid receiving adapters with tube clamps in a modular prosthetic limb prosthesis.	4053646SchraubAdD4
Threaded Adapter A22-St, A22-Ti, A23-St, A23-Ti, A25-Ti M36-Aapter A87	The thread adapters connect pyramid adapters or pyramid receiving adapters with a M36-thread or 30 mm- tube in a modular prosthetic limb prosthesis.	4053646Schraubadaption9V
...		
Shifting Adapter VA1-Ti, VA2-Ti, VA9-Al	The shifting adapters are for integration into a modular prosthetic limb prosthesis to enable axial shifting.	4053646VerschiebeAdYU
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Polycentric Knee Joint JT20-PYR, JT20-M36, JT22-PYR, JT22-M36, JT20S-PYR, JT20S-M36, JT22S-PYR, JT22S-M36	The knee joints are the connection between a prosthetic socket and a modular prosthetic limb prosthesis with polycentric knee function.	4053646PolyCD
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Geriatric - Knee Joint JT01 Monocentric Knee Joint JT02-St, JT02-Ti Lightweight Knee Joint JT03 Safety Knee Joint JT05-St, JT05-Ti, JT09	The knee joints are the connection between a prosthetic socket and a modular prosthetic limb prosthesis with monocentric knee function.	4053646monoKnie53
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SoftskinAir®-Liner S30-Air, S30CL-Air, SC30-Air, S40-Air, Sport-Air, S40CL-Air, SC40-Air, S50-Air, S50CL-Air, STF-Air, S-2L-Air Softskin-Liner S30, S30CL, SC30, S40, S40CL, SC40, S50, S50CL, STF, S-2L	The SoftSkin Liners are the connection between the prosthetic socket and the residual limb. The SoftSkin Liners with Air function have additional transportation of moisture from the skin through the liner wall.	4053646SoftskinWQ

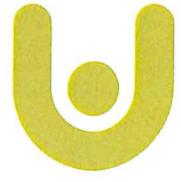


Silicone-Liner L03-[size], L20-[size]		
Distal-Cup L01-[size]	The silicone products (L01, L03, L14, L15, and L20) are used to bed the residual limb.	4053646Silikon4E
Silicone Distal End Pad L14-1, L14-2, L15-1, L15-2		
Vacuum-Jet VJ1, VJ2		
Lat Rubber Valve V02		
...		
Socket Valve V08, V09, V09-A, V10, V10-A, V13		4053646Ventile6B
Valve V18, V20, V21, V22		
Locking Device ShL1, ShL20, ShL3A-2, ShL5B, ShL50B		
Modular Locking Device ShL40A, ShL40B	The locking devices and pulling-in mechanisms are used to connect the prosthetic liner with the prosthetic socket.	4053646ShLFM
Pulling-In Mechanism EM		
Torsion Orthosis/ Pelvic Band OB100-[size], OB101-[size], OB102-[size]	The Torsion Orthosis is a rotation-rod-orthosis for dynamic torsion of the full leg.	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	The DAHO Hand orthosis are a modular system for treatment after surgery, injuries or illnesses of the fingers and hand. The DAHO type 4 and 4P are designed to immobilize the wrist, fingers and thumb joints.	4053646DAHOW2

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
Responsible Person §15 MDR

Ingo Schneider
Managing Director



Version history:

<i>Version</i>	<i>Effective Date</i>	<i>Reason for Revision</i>
000	25. May 2021	New Document
001	01. October 2021	Addition SRN; SoftskinAir Duo/ Softskin Duo added
002	12. January 2023	Change from S-Duo-Air/ S-Duo to S-2L-Air/ S-2L
003	09.10.2023	SC30-Air and SC30 added