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Declaration of Conformity

EMDN Code : Y061299

Issue Date: May 22, 2023

EMDN Description: Lower extremity orthoses - other

Valid Date: Dec. 31, 2025

This declaration of conformity is issued under the sole responsibility of the manufacturer:

La Pointique Int'l Ltd., address at: 701 Fifth Ave, Suite 4200, Seattle, WA 98104, USA

Single registration number (SRN): US-MF-000005204

Authorised Representative: MT Promedt Consulting GmbH, address at: Ernst-Heckel-Straße 7,
D-66386 St. Ingbert Germany Single registration number (SRN): DE-AR-000000085

The basic UDI-DI: 8402695CL102PN

We herewith declare that the products as referred to in Attachment I are in conformity with the requirements set out in the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

Conformity Assessment Procedure: MDR (EU) 2017/745 Art 52. (7), ANNEX II (Technical documentation) & ANNEX III (Technical documentation on post-market surveillance)

Risk Classification of the Product: Class I Rule: MDR (EU) 2017/745, Annex VIII, Section 4, 4.1, Rule 1 "All non-invasive devices are classified as class I."

Applied Standards: EN ISO13485:2016, EN1041:2008, EN ISO14971:2019, EN ISO 15223-1:2021,
EN ISO 10993-1:2009, EN ISO10993-5:2009, EN ISO 22523:2006, EN 62366:2008,
ISO 10993-10:2021, ISO 9001:2015

Intended purpose: The devices soothe pain and resolve strains, sprains, overstretch injuries, and joint malalignments. They provide compression and support injuries by keeping joints in a neutral position. They also retain heat to alleviate soft tissue adhesions.

May 22, 2023/ Seattle

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Date/Place


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Jackson Chiang
President



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Attachment 1

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EMDN Description: Lower extremity orthoses – other

Knee

Reference number	Product Trade name
170XT	Knee Brace 1.0
171XT	Knee Brace 2.0
176XT	Target Compression Knee Sleeve
272Z	Leg Compression Sleeve
507CA	Knee Guard
510CP	Knee Stabilizer
516CP	Knee Support (Closed Patella)
518CP	Knee Support (Open Patella)
533CA	Knee Support with Posterior Reinforcement Straps
558CA	Knee Support
569CP	Patella Support
579CA	Patella Tracking Support
581	Dual Patella Strap
588CP	Knee Support
601	Knee Support
606	Knee Guard (Adult Size)
631	Knee Wrap
639	X-Knee Support
641	Knee Support
647	Knee Support
651	Elastic Bandage
667	Knee Support
706	Knee Support (Closed Patella)
706CA	Knee Support
707	Standard Knee Support (Closed Patella)
708	Standard Knee Support (Open Patella)
708CA	Knee Support
709	Knee Stabilizer
710	Hinged Knee Stabilizer
710A	Polycentric Rehab Stabilizer
719CA	Knee Support with Silicone Pad
720	Knee Support (with Vertical Buttress)
721	Patella Stabilizer
733	Knee Support with Stays
733CA	Knee Support with Stays
734	Knee Stabilizer
756	Closed Patella Knee Support
756CA	Closed Patella Knee Support



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758	Open Patella Knee Support
758CA	Open Patella Knee Support
760	Patella Strap
769	Patella Brace
781	Patella Strap
782	Open Patella Knee Support (with Stays)
788	Open Patella Knee Support
788CA	Knee Support
941	Knee Support
951	Knee Support
961	Elastic Knee Sleeve
988	Nanometer Knee Support
991	Ceramic Knee Support
647KM	Knee Support
667KM	Knee Support
733KM	Knee Support with Stays
756KM	Closed Patella Knee Support
758KM	Open Patella Knee Support
760KM	Patella Strap
788KM	Open Patella Knee Support
790KM	Knee Support with Movable Pads
CT71	Light Shield Knee Brace
CT72	Light Shield Adjustable Knee Brace
CT73	Light Shield Patella Strap
533CAR1	COOLPRENE X Knee Support with Patella Support Ring and Extra Side and Front Supports
558CAR1	COOLPRENE X Knee Support with Side Contour Seams
706CAR1	COOLPRENE X Knee Sleeve
708CAR1	COOLPRENE X Knee Sleeve with Open Patella
719CAR1	COOLPRENE X Knee Sleeve with Open Patella and Extra Patellar Tendon Support
733CAR1	COOLPRENE X Knee Support with Patella Support Ring and Extra Side Supports
756CAR1	COOLPRENE X Knee Support
758CAR1	COOLPRENE X Knee Support with Patella Support Ring (Added Length)
788CAR1	COOLPRENE X Knee Support with Patella Support Ring
733CN	COOLPRENE Knee Support with Patella Support Ring and Extra Side Supports
756CN	COOLPRENE Knee Support



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758CN	COOLPRENE Knee Support with Patella Support Ring (Added Length)
781CN	COOLPRENE Patella Strap
788CN	COOLPRENE Knee Support with Patella Support Ring
790CN	COOLPRENE Knee Support with Movable Pads
647R1	Knee Sleeve
667R1	Leg Sleeve
760R1	Patella Strap
FT75CA	COOLPRENE X Knee Sleeve
G-B75XT	DOMINATE B75 X Knit MG Knee Sleeve
G-K95XT	DOMINATE K95 X Knit MG Leg Sleeve
SP70XT	X KNIT Knee Support with Extra Side Supports

Ankle

Reference number	Product Trade name
110XT	Ankle Support 1.0
116XT	Target Compression Ankle Sleeve
203Z	Ankle Support Compression Quarter Socks
514CP	Ankle Support
528	Ankle Support with Plastic Stay
528CP	Ankle Support
529	Achilles Tendon Support
586	V-Guard Volleyball Ankle Brace
597	Ankle Brace
604	Ankle Support
634	Ankle Wrap
650	Ankle Support
704	Ankle Support
704CA	Ankle Support
728	Ankle Support (With Strap)
728CA	Ankle Support
729	Ankle Support (With Silicone Pad)
757	Ankle Support
757CA	Ankle Support
764	Ankle Support
768	Adjustable Ankle Support
775	Ankle Support (With Stay and Strap)
787	High Performance Ankle Brace
944	Ankle Support
954	Ankle Support
964	Elastic Ankle Support
987	Nanometer Ankle Support
994	Ceramic Ankle Support
CT11	Light Shield Ankle Brace



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CT12	Light Shield Adjustable Ankle Brace
757KM	Ankle Support
768KM	Adjustable Ankle Support
704CAR1	COOLPRENE X Ankle Sleeve with Open Heel
757CAR1	COOLPRENE X Ankle Brace with Figure 8 Straps
757CN	COOLPRENE Ankle Support with Open Heel
768CN	COOLPRENE Ankle Support with Rear Adjustable Strap
FT15CA	COOLPRENE X Ankle Sleeve with Open Heel

Shin

Reference number	Product Trade name
204Z	Ankle Support Compression Socks
270Z	Calf Compression Sleeve
545CP	Shin Support
635	Shin Wrap
718	Shin and Calf Sleeve
778	Shin and Calf Support
945	Shin Sleeve
955	Shin Support
957	Elastic Support Stoking
CT21	Light Shield Calf Brace
SLU3301Z	Run Calf Compression Sleeve
G-R90XT	DOMINATE R90 X Knit MG Calf Sleeve
G-R91XT	DOMINATE R91 X Knit MG Calf Sleeve

Thigh

Reference number	Product Trade name
271Z	Thigh Compression Sleeve
515CP	Thigh Support
602	Thigh Support
627	Compression Sports Shorts
648	Thigh Support
705	Thigh Support
705CA	Thigh Support
755	Thigh Support
952	Thigh Support