

Declaration of Conformity

Product Designation: Support

Issue Date: May 26, 2021

UMDNS- Code: 13-858

Valid Date: May 26, 2022

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: Altenhofstrasse 80,

D-66386 St. Ingbert Germany

Single registration number (SRN): DE-AR-000000085

The basic UDI-DI: Not yet published.

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 ANNEX II (Technical documentation) & ANNEX III (Technical documentation on post-market surveillance)

Risk Classification of the Product: Class I Rule: MDR (EU) 2017745, Annex VIII, Section 4, 4.1, Rule 1"All non-invasive devices are classified as class I."

Applied Harmonized Standards: EN ISO9001:2015, EN ISO13485:2016, EN1041:2008,

EN ISO14971:2012, EN ISO 15223-1:2016, EN ISO10993-5:2009, EN ISO 22523:2006

Intended purpose: The support soothes pain and resolves strains, sprains, overstretch injuries, and joint malalignments. It provides compression and supports injuries by keeping joints in a neutral position. It also retains heat to alleviate soft tissue adhesions.

May 26, 2021/Seattle

Jackson Chiang

Date/Place

Mr. Jackson Chiang

President



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Attachment 1

Product Designation: Support

UMDNS- Code: 13-858

Shoulder

Reference number	Product Trade name
538CP	Shoulder Support
738	Shoulder Support
754	Shoulder Support
958	Shoulder Support
538CA	Shoulder Support

Knee

Reference number	Product Trade name	
170XT	Knee Brace 1.0	
171XT	Knee Brace 2.0	
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	

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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
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
176XT	Target Compression Knee Sleeve

Ankle

Reference number	Product Trade name
110XT	Ankle Support 1.0
203Z	Ankle Support Compression Quarter Socks
204Z	Ankle Support Compression 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

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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
957	Elastic Support Stoking
964	Elastic Ankle Support
987	Nanometer Ankle Support
994	Ceramic Ankle Support
CT11	Light Shield Ankle Brace
CT12	Light Shield Adjustable Ankle Brace
757KM	Ankle Support
768KM	Adjustable Ankle Support
116XT	Target Compression Ankle Sleeve

Shin

Reference number	Product Trade name
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
CT21	Light Shield Calf Brace
SLU3301Z	Run Calf Compression 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

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705CA	Thigh Support	
755	Thigh Support	
952	Thigh Support	

Clavicle

Reference number	Product Trade name	
901	Clavic Brace	
929	Posture Support Brace	

Rib

Reference number	Product Trade name
910M	Rib Belt
910F	Rib Belt