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## Declaration of Conformity

EMDN Code : Y060699

Issue Date: May 22, 2023

EMDN Description: Orthoses, upper extremity - 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: 8402695CL103PQ

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)

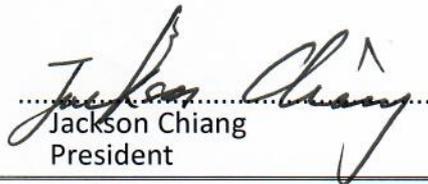
Risk Classification of the Product: Class I    Rule: MDR (EU) 2017/745, Annex VIII, Section 4, 4.1, Rule 1 "All non-invasive devices are classified as class I."

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

.....  
Date/Place

  
.....  
Jackson Chiang  
President



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Attachment 1

EMDN Code : Y060699

EMDN Description: Orthoses, upper extremity - other

Shoulder

| Reference number | Product Trade name           |
|------------------|------------------------------|
| 538CA            | Shoulder Support             |
| 538CP            | Shoulder Support             |
| 738              | Shoulder Support             |
| 754              | Shoulder Support             |
| 958              | Shoulder Support             |
| 538CAR1          | COOLPRENE X Shoulder Support |

Elbow

| Reference number | Product Trade name               |
|------------------|----------------------------------|
| 150XT            | Elbow Support1.0                 |
| 250Z             | Elbow Compression Sleeve         |
| 251Z             | Arm Compression Sleeve           |
| 513CP            | Elbow Support                    |
| 522CA            | Elbow Guard                      |
| 551              | Tennis/Golf Elbow Brace          |
| 551CP            | Tennis/Golf Elbow Support        |
| 603              | Elbow Support                    |
| 632              | Elbow Wrap                       |
| 649              | Elbow Support                    |
| 668              | Elbow Support                    |
| 701              | Tennis Elbow Support             |
| 702              | Elbow Support                    |
| 723              | Tennis Elbow Support(With Strap) |
| 724              | Elbow Support                    |
| 751              | Tennis and Golf Elbow Wrap       |
| 751CA            | Elbow Support                    |
| 759              | Elbow Wrap                       |
| 943              | Elbow Support                    |
| 953              | Elbow Support                    |
| 963              | Elastic Elbow Support            |
| 989              | Nanometer Elbow Support          |



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|---------|--|
| 993     | Ceramic Elbow Support                          |
| SL51    | Performance Arm Sleeve                         |
| CT51    | Light Shield Elbow Brace                       |
| 751KM   | Elbow Support                                  |
| 759KM   | Elbow Wrap                                     |
| 668KM   | Elbow Support                                  |
| 751CAR1 | COOLPRENE X Elbow Wrap for Tennis / Golf Elbow |
| 751CN   | COOLPRENE Elbow Wrap for Tennis / Golf Elbow   |
| 759CN   | COOLPRENE Elbow Support                        |
| 668R1   | Arm Sleeve                                     |
| FT55CA  | COOLPRENE X Elbow Sleeve                       |

Wrist

| Reference number | Product Trade name     |
|------------------|------------------------|
| 130XT            | Wrist Brace 1.0        |
| 521CA            | Wrist Splint           |
| 535              | Breathable Wrist Brace |
| 535CP            | Wrist Splint           |
| 550              | Rigid Wrist Brace      |
| 552              | Wrist Brace            |
| 553CP            | Wrist Support          |
| 563CA            | Wrist/Thumb Support    |
| 576              | Wrist/Thumb Support    |
| 605              | Palm Brace             |
| 633              | Wrist Wrap             |
| 643              | Wrist Support          |
| 652              | Elastic Bandage        |
| 703              | Wrist Support          |
| 725              | Wrist Splint           |
| 725CA            | Wrist/Forearm Brace    |
| 726              | Wrist Wrap             |
| 739              | Wrist Wrap             |
| 752              | Wrist/ Thumb Support   |
| 753              | Wrist Wrap             |
| 753CA            | Wrist Support          |



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|---------|---|
| 763     | Wrist/Thumb Support                             |
| 776     | Wrist/Thumb Support                             |
| 904     | Splint Wrist Brace                              |
| 959     | Wrist Support                                   |
| 969     | Elastic Wrist Support                           |
| 986     | Nanometer Wrist Support                         |
| 521KM   | Wrist Splint                                    |
| 563KM   | Wrist/Thumb Support                             |
| 739KM   | Wrist Wrap                                      |
| 753KM   | Wrist Wrap                                      |
| 563CAR1 | COOLPRENE X Wrist Support with Thumb Stabilizer |
| 753CAR1 | COOLPRENE X Wrist Wrap                          |
| 739CN   | COOLPRENE Wrist Support with Thumb Loop         |
| 753CN   | COOLPRENE Wrist Wrap                            |
| FT35CA  | COOLPRENE X Wrist Support                       |