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Declaration of Conformity

EMDN Code : Y060399

Issue Date: May 22, 2023

EMDN Description: Spine 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: 8402695CL104PS

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

EMDN Code : Y060399

EMDN Description: Spine orthoses – other

Rib

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

Waist

Reference number	Product Trade name
160XT	Back Support 1.0
161XT	Back Support 2.0
573CA	Back Support
573CP	Back Support
575	Nano Lumbar Support
711	Waist Trimmer (One Side Nylon)
711A	Waist Trimmer (Two Sides Nylon)
715	Magnetic Waist Support
727	Back Support (With Stays)
727CA	Back Support
771	Back Support (High Back)
772	Back Support (High Back with Stays)
773	Sacro Lumbar Support
902	Sacro Lumbar Support
903	Sacro Lumbar Support
907	Magnetic Waist Belt
908	Abdominal Binder
912	Industrial Back Support
914	Sacro Lumbar Support
916	Lumbar Support With Stays
919	Back Support (With Stays)
919KM	Back Support with Stays
920	Back Support (With Removable Pad)
937	Sacro Lumbar Support With Stays



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573CAR1	COOLPRENE X Back Support with Extra Waist Support and Bilateral Compressive Straps
727CAR1	COOLPRENE X Back Support with Extra Waist Support
919R1	Back Support with Extra Lumbar Support and Bilateral Compressive Straps
SP61XT	X KNIT Back Support with Extra Lumbar Support