

Declaration of Conformity

Product Designation: Support, Torso

Issue Date: May 26, 2021

UMDNS- Code: 18-030

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, torso reduces waist pain from sudden movements by holding the area in place. It keeps an injured back compressed.

May 26, 2021/Seattle

Jackson Chiang

Date/Place

Mr. Jackson Chiang President

LA POINTIQUE INT'L LTD.



Attachment 1

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Reference number	Product Trade name
160XT	Back Support 1.0
161XT	Back Support 2.0
573CP	Back Support
575	Nano Lumbar Support
711 A	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
573CA	Back Support