CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Orthomerica Products, Inc.

(FIN F001562)

Main Site: 6333 N. Orange Blossom Trail

Orlando, FL, 32810, USA

Additional Site: 6333 N. Orange Blossom Trail, Suite 118

Orlando, FL, 32810, USA

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

Main site: Design, development and manufacture of prefabricated, custom-to-measurement, and custom-to-cast orthopedic orthoses, including contract manufacture, installation and service of associated software.

Additional site: Warehousing of raw materials

Certificate Number:
0087702-03

Initial Certification Date:
2019-02-28

Date of Certification Decision:
2024-07-13

Certification Effective Date:
2024-07-13

Certification Expiry Date:
2025-02-27

Calin Moldovean
President, Business Assurance

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