

# Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Orthomerica Products Inc.	6333 North Orange Blossom Trail Orlando, FL 32810 USA	US-MF-000009882

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Numbers
Lumbostar Plus Orthosis	3289-ORMED to 3296-ORMED
Intended Purpose	Basic UDI-DI
Provide stability and abdominal support without compromising respiration or interfering with activities of daily living. Indications include acute and chronic low back pain, post-operative support, and activity-related low back pain. It can be effective for patients that have problems tolerating xiphoid height spinal systems, e.g., obese patients, those with a short stature, women in late pregnancy and patients with respiratory problems.	Being Assigned UDI 00195003003087 – 00195003003117 00195003040051 – 00195003003162 00195003003186 – 00195003003216 00195003003247 – 00195003003278

RISK CLASS FOR DEVICES		
Device Classification		Common Specifications / Standards
Class:	1	EN ISO 13485:2016 EN ISO 15223-1
Rule:	1	

Orthomerica declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745

**COMPANY REPRESENTATIVE:** Najiba Katir

**TITLE:** Regulatory Compliance

**SIGNATURE:** *Najiba Katir*

**PLACE:** Orlando

**DATE:** 06/08/2021