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

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