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 Orthosis	3199-ORMED to 3206-ORMED 3209-ORMED to 3216-ORMED
Intended Purpose	**Basic UDI-DI**
Indications include acute and chronic low back pain, spondylolisthesis and post-op low lumbar laminectomy. Optimal for patients requiring support for everyday activities such as lifting, long periods of standing, work related motions, golf and gardening.	Being Assigned UDI 00195003002103 – 00195003002127 00195003002141 – 00195003002165 00195003002189 – 00195003002202 00195003002226 – 00195003002240 00195003002264 – 00195003002288 00195003002301 – 00195003002325 00195003002349 – 0195003002363 00195003002387 - 00195003040754

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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