

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 – 00195003002363 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