

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
Fracture Brace Socks: Femoral Socks - Tibial Socks - Upper Extremity Socks - Hip Sock - Pediatric AFO Socks - Seamless over the Calf Socks	4100 to 4108 4109, 4110, 4112, 4115 4130, 4132, 4134, 4135 - 4120 4140, 4141, 4142 4150, 4151, 4152, 4153
Intended Purpose	Basic UDI-DI
Improve comfort and hygiene when wearing a fracture brace.	Being Assigned UDI 00195003076333 – 00195003076326 – 00195003076319 00195003076296 – 00195003076272 – 00195003076265 00195003076234 – 00195003076142 – 00195003076135 00195003076302 – 00195003076340 – 00195003076357 00195003076401 – 00195003076487 – 00195003076494 00195003076500 – 00195003076630 – 00195003076371 00195003076654 – 00195003076258 – 00195003076210 00195003076203 – 00195003076159 – 00195003076173 00195003076166

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: 04/08/2021

