

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
Newport 4 Pelvic and Thigh Components and Liners	3870, 3871, 3872, 3873 3810.02, 3811.02, 3812.02, 3813.02, 3770.06, 3771.06, 3772.06, 3773.06, 3775.06, 3776.06, 3777.06, 3778.06 3820.02, 3821.02, 3822.02, 3823.02, 3825.02, 3826.02, 3827.02, 3828.02
Intended Purpose	Basic UDI-DI
Thigh component adjusts with clamping disc to accommodate varying shapes and prevent knee flexion impingement. Preset, quick release closures ensure same fit each time Patented clamping technology on pelvic band adjusts to male or female anatomy and a wide range of circumferences Universal pelvic fit.	Being Assigned UDI 00195003005081- 00195003005098 – 00195003005104 00195003005111 - 00195003073608 – 00195003008082 00195003008174 - 00195003007825 – 00195003004862 00195003004909 – 00195003004947 - 00195003004985 00195003005012 - 00195003005036 – 00195003005050 00195003005074 - 00195003073615 – 00195003073400 00195003073516 - 00195003007818 – 00195003073493 00195003008075 - 00195003008167 – 00195003073486

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

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

