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 Orthosis Newport 4 Pelvic and Thigh Components and Liners – Joints	3742, 3743, 3744, 3745, 3746, 3747, 3748, 3749, 3742.03, 3743.03, 3744.03, 3745.03, 3746.03, 3747.03, 3748.03, 3749.03 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 4320, 4321, 4322, 4327
Intended Purpose	**Basic UDI-DI**
Post-op hip revision patients Primary arthroplasty patients at risk to dislocate, (e.g., patients with congenital hip dysplasia or spastic/tight adductors) As a prophylaxis to reinforce hip precautions Inoperable hip patients at risk	Being Assigned UDI 00195003004756 - 00195003004763 - 00195003006972 - 00195003004770 00195003004787 - 00195003004794 - 00195003004800 - 00195003004817 00195003073424 - 00195003073479 - 00195003073332 - 00195003073349 00195003073370 - 00195003007764 - 00195003073547 - 00195003073714 00195003005081 - 00195003005098 - 00195003005104 - 00195003005111 00195003073608 - 00195003008082 - 00195003008174 - 00195003007825 00195003004862 - 00195003004909 - 00195003004947 - 00195003004985 00195003005012 - 00195003005036 – 00195003005050 - 00195003005074 00195003073615 - 00195003073400 - 00195003073516 - 00195003007818 00195003073493 - 00195003008075 - 00195003008167 - 00195003073486 00195003005746

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:** 19/08/2021

CE