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	3742, 3743, 3744, 3745, 3746, 3747, 3748, 3749, 3742.03, 3743.03, 3744.03, 3745.03, 3746.03, 3747.03, 3748.03, 3749.03
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

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:** 05/08/2021

CE