

# 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
<b>Class:</b>	1	EN ISO 13485:2016 EN ISO 15223-1
<b>Rule:</b>	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

