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 3 A R C KIT	3670, 3671, 3672, 3672 X, 3672 XX 3673, 3674, 3675, 3675 X, 3675 XX,
Intended Purpose	**Basic UDI-DI**
Maintain the affected limb in either internal or external rotation. It is indicated for primary or revision total hip arthroplasty patients at risk to dislocate in an anterior or posterior direction. The ARC can be retrofitted on any adult Newport System	Being Assigned UDI 00195003004688 – 00195003007634 00195003061179 – 00195003004718 00195003004725 – 00195003061117 00195003004695 – 00195003004701 00195003004732 - 00195003004749

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	1	EN ISO 13485:2016 EN ISO 15223-1:2016
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:** 20/07/2021