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 III Pelvic and Thigh Components Liners – Strap Kit	3650, 3351, 3652, 3653, 3655, 3656, 3657, 3658, 3650.01, 3651.01, 3652.01, 3653.01, 3650.02, 3651.02, 3652.02, 3653.02, 3769.05, 3770.05, 3771.05, 3772.05. 3773.05, 3774.05, 3775.05, 3776.05, 3777.05, 3778.05 3810.05, 3811.05, 3812.5, 3813.05, 3810.06, 3811.06, 3812.06, 3813.06 – 3808 - 3808.01 - 3809
Intended Purpose	**Basic UDI-DI**
Allow for the rapid adjustment for both hip circumference and hip development while the patient is wearing the Newport III orthosis. Control of adduction/flexion/extension	Being Assigned UDI 00195003004510 – 00195003004541 - 00195003004572 - 00195003004602 00195003004633 - 00195003004640 00195003004657 – 00195003004664 00195003004527 - 00195003004558 - 00195003004589 - 00195003004619 00195003060257 – 00195003006705 - 00195003006712 - 00195003060967 00195003004824 - 00195003004855 - 00195003004893 – 00195003004930 00195003004978 - 00195003004992 – 00195003005005 - 00195003005029 00195003005043 – 00195003005067 – 00195003061698 - 00195003061643 00195003060431 – 00195003060387 - 00195003061674 – 00195003006729 00195003006729 – 00195003007658 – 00195003061346- 00195003061339 00195003061308

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

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