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	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Numbers**
California Compression Orthosis 8" and 10" And Combo	3199,3200,3201,3202,3203,3204,3205, 3206 3209,3210,3211,3212,3213,3214,3215,3216 3329,3330,3331,3332,3333,3334,3335,3336 3339,3340,3341,3342,3343,3344,3345,3346
Intended Purpose	**Basic UDI-DI**
Indications include acute and chronic low back pain, spondylolisthesis and post-op low lumbar laminectomy. Optimal for patients requiring support for everyday activities such as lifting, long periods of standing, work related motions, golf and gardening.	Being Assigned UDI 00195003002097 – 00195003002110 – 00195003002134 00195003002158-- 00195003002172 – 00195003002196 00195003002219 – 00195003002233 - 00195003002257 00195003002271 - 00195003002295 – 00195003002318 00195003002332 – 00195003002356 - 00195003002370 – 00195003002394 – 00195003003421 – 00195003003438 00195003003445 – 00195003003452 – 00195003003469 00195003003476 – 00195003003483 – 00195003003490 00195003003506- 00195003003513 – 00195003003520 00195003003537 – 00195003003544 – 00195003003551 00195003003568 - 00195003003575

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:** 28/10/2024

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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	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Numbers**
California Hip Orthosis	From 3960 to 3963 - 3965 to 3968 3970 to 3973 and 3976 to 3979 505-4094, 3955, 3955.01
Intended Purpose	**Basic UDI-DI**
Prevent risk of dislocation and facilitate pelvic and thigh control. Hip joint settings provide a strong flexion/extension stop with mild, adjustable resistance to adduction	Being Assigned UDI 00195003005401 – 00195003005418 00195003005425 – 00195003005432 00195003005449 – 00195003005456 00195003005463 – 00195003005470 00195003005487 – 00195003007849 00195003005494 – 00195003005500 00195003005517 – 00195003005524 00195003005531 – 00195003005548 00195003006996 – 00195003005395

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:** 28/10/2024

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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	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Numbers**
California Low Profile Orthosis California Low Profile LC Orthosis	3289 to 3296 3289.01 to 3296.01
Intended Purpose	**Basic UDI-DI**
Provide stability and abdominal support without compromising respiration or interfering with activities of daily living. Indications include acute and chronic low back pain, post-operative support, and activity-related low back pain. It can be effective for patients that have problems tolerating xiphoid height spinal systems, e.g., obese patients, those with a short stature, women in late pregnancy and patients with respiratory problems.	Being Assigned UDI 00195003003063 – 00195003003070 00195003003094 – 00195003003100 00195003003124 – 00195003003131 00195003003148 – 00195003003155 00195003003179 – 00195003007894 00195003003193 – 00195003003209 00195003003223 – 00195003003230 00195003003254 – 00195003003261

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:** 12/08/2024

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Declaration of Conformity

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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	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Numbers**
Universal Humeral Fracture Brace kit Bi-valved Humeral Fracture Brace kit	1079, 1080, 1081, 1082, 1083, 1069, 1070, 1071, 1072, 1073, 1350, 1351, 1352, 1353, 1355, 1356, 1357, 1358
Intended Purpose	**Basic UDI-DI**
Manage mid-shaft diaphyseal humeral fractures while allowing shoulder range of motion, maintaining compression and limiting distal migration	Being Assigned UDI 00195003000369 – 00195003000376 00195003000383 – 00195003006606 00195003000390 – 00195003000314 00195003000321 – 00195003000338 00195003000345 – 00195003000352 00195003000796 – 00195003000802 00195003000819 – 00195003000826 00195003000833 – 00195003000840 00195003000857 – 00195003000864

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:** 10/02/2024

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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	Westervoortsedijk 60 6827 AT Arnhem 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
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:** 28/10/2024

Declaration of Conformity

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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	Westervoortsedijk 60 6827 AT Arnhem 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 Hip Joints	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 4262.05, 4264.05, 4326, 4240, 4241, 4210.01, 4211.01, 3768.02A
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 - 00195003005593 - 00195003005609 – 00195003005739 00195003008006 – 00195003061315 – 00195003060295 –00195003060325 00195003060769

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:** 28/10/2024

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Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Numbers**
Newport III Orthosis	3640, 3641, 6342, 6343, 3645, 3646, 3647, 3648, 3640.40, 3641.41, 3642.42, 3643.43
Intended Purpose	**Basic UDI-DI**
Post-operative hip revision patients Primary arthroplasty patients at risk to dislocate Patients needing stability after dislocation Inoperable patients requiring hip stabilization Patients who can benefit from a hip orthosis to reinforce hip precautions	Being Assigned UDI 00195003004350 - 00195003004381 00195003004411 - 00195003004442 00195003004473 - 00195003004480 00195003004497 - 00195003004503 00195003004367 - 00195003004398 00195003004428 - 00195003004459

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

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COMPANY REPRESENTATIVE: Najiba Katir

TITLE: Regulatory Compliance **SIGNATURE:** Najiba Katir

PLACE: Orlando **DATE:** 28/10/2024

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Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem 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:** 19/08/2024

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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	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Numbers**
Shoulder Humeral FX kit	1089, 1090, 1091, 1092, 1093
Intended Purpose	**Basic UDI-DI**
Manage humeral fractures while allowing full shoulder range of motion thanks to shoulder caps which limit distal migration. Can be trimmed to allow elbow range of motion	Being Assigned UDI 00195003000406 – 00195003000413 00195003000420 – 00195003006613 00195003000437

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

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- Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Najiba Katir

TITLE: Regulatory Compliance **SIGNATURE:** Najiba Katir

PLACE: Orlando **DATE:** 10/09/2024

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