

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
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: 19/08/2021

