

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 Soft Spinal Orthosis	3306 to 3312 - 3360 to 3366 3299 to 3305 - 3350 to 3356 3299.28, 3299.02, 2013, 2014, 3299.04, 3299.05
Intended Purpose	Basic UDI-DI
Alleviate pain, limit undesirable motion, and provide circumferential pressure to stabilize the spine. Effective for more superior spinal problems between T7 and L3, by adding either an anterior, posterior, or combined upper thoracic component.	Being Assigned UDI 00195003003353 – 00195003003360 00195003003377 – 00195003003384 00195003003391 – 00195003003407 00195003003414 – 00195003067591 00195003068321 – 00195003003612 00195003003629 – 00195003014908 00195003071109 – 00195003072243 00195003003285 – 00195003003292 00195003003308 – 00195003003315 00195003003322 – 00195003003339 00195003003346 – 00195003019248 00195003019750 – 00195003003582 00195003003599 – 00195003003605 00195003069908 – 00195003068123 00195003054102 – 00195003079051 00195003001649 – 00195003001663

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: 29/07/2021