

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-00000116	+31.70.345.8570 EmergoEurope@ul.com		

PRODUCT IDENTIFICATION		
Product Name	Code / Catalog Numbers	
VersaROM Hip	11-3333	
Intended Purpose	Basic UDI-DI	
Minimally invasive hip procedures	Being Assigned	
Labral repair, with or without gluteus medius repair UDI 00195003006583		
ROM Control following primary or hip revision surgery		
Post-op proximal hamstring repair		

RISK CLASS FOR DEVICES				
Device Classif	ication	Common Specifications / Standards		
Class:	1	EN ISO 13485:2016 EN ISO 15223-1		
Rule:	1	EN 13O 13225-1		

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: 01/07/2021

