

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
Polaris Rehab Euro	E8499 to E8504 E8499.01 to E8504.01 E8499.02 to E8504.02
Intended Purpose	Basic UDI-DI
Range-of-motion control or immobilization of the knee for longer term support during active recovery stages. Flexion/extension control with no tools.	Being Assigned UDI 00195003077750 -00195003077743 00195003077583 -00195003077613 00195003077644 – 00195003077675 00195003078245 – 00195003077729 00195003077590 – 00195003077620 00195003077651 – 00195003077576 00195003078498 - 00195003077774 00195003078337 -00195003078399 00195003077781 - 00195003078061

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: 04/08/2021

