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**
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:** 17/08/2021

CE