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**
Shoulder Humeral FX kit Soft Shoulder Humeral FX kit	1089, 1090, 1091, 1092, 1093 1229, 1230, 1231, 1232, 1233
Intended Purpose	**Basic UDI-DI**
Manage humeral fractures while allowing full shoulder range of motion thanks to shoulder caps which limit distal migration. Can be trimmed to allow elbow range of motion. Soft version effective for humeral diaphyseal fractures	Being Assigned UDI 00195003000406 – 00195003000413 00195003000420 – 00195003006613 00195003000437 – 00195003000741 00195003000758 – 00195003000765 00195003000772 - 00195003000789

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: 12/07/2021

CE