EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Medsource Factory, Inc. #160 Jinsheng Dong Lu, Jintan District,Changzhou City,Jiangsu Province, 213200 China
Trademark:	Unitedmed 珂 迈 迪
SRN:	Not available yet
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8 80807 Munich, Germany
SRN:	**DE-AR-000000087**
Trade name:	Splints
Product Name:	Splints
Models:	26010.26011.26012.26013.26014
Basic UDI：	6975293692601189
Classification acc. to MDR Ax. VIII:	Class I, rule I
Applied Common Specifications / Standards:	EN ISO 14971： 2019
Conformity assessment procedure:	N.A.
CE certificate No.:	N.A.
Name and ID of the Notified Body:	N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Signature of issue person: Lu GuoFang

Jiangsu, May. 16,2022

Name： Lu Guofang

Position： General Manager