

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:



SRN: Not available yet
MedPath GmbH

European Representative: 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 / EN ISO 14971: 2019
Standards:

Conformity assessment

procedure: N.A.

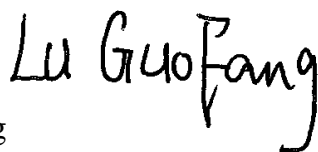
CE certificate No.: N.A.

Name and ID of the Notified N.A.

Body:

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:

A handwritten signature in black ink, appearing to read "Lu Guofang", is written over a light blue grid background.

Jiangsu, May. 16, 2022

Name: Lu Guofang

Position: General Manager