EU Declaration of Conformity

Manufacturer:	Xiamen J-Brace Medical Equipment Co., Ltd. 2F, 179#,Tong'an Park, Tong'an Industrial Cluster, Xiamen 361100 China
SRN:	/
European Representative:	Riomavix Sociedad Limitada Calle de Almansa 55, 1D, Madrid 28039 Spain
SRN:	ES-AR-000001202
Product Name:	Finger Splint
GMDN Code:	41456
UDI-DI:	/

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.
The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:
EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ISO 188:2011, ISO 21171:2006. MDCG 2019-15.

Signature:

Name: Jesse

Position: General Manager

Place/date China, Mar. 10th, 2021