



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: JIANGSU RIXIN MEDICAL EQUIPMENT CO., LTD.
Address: No.427 Yangjin Road, Jinfeng, Zhangjiagang, Jiangsu Province, China
SRN: CN-MF-000008761

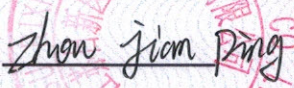
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product category: See Annex

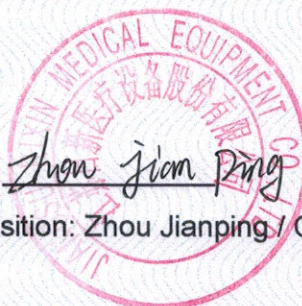
Classification Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971: 2012
EN 1041:2008+A1:2013
EN ISO 15223-1: 2016

Signature: 
Name / Position: Zhou Jianping / GM

Date: 2021.11.1
Place: JiangSu / China



ANNEX



Product Name	Model	Basic UDI-DI	Picture
Splint	BS-01	697444205BS01GQ	