DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019/A11:2021
ISO 15223-1: 2021/Amd 1:2025
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009/A11:2025
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-009.
All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

File No.: MDR-TCF-009-08

Manufacturer

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

Product Information

Name: Splint
Model: PS-01, PM-01, BS-01(L,M,S), AS-01, AS-02, AS-03, AS-04, AS-05D, AS-05F, AS-05H, AS-05K,TS-01, TS-02, AM-01
EMDN: M03050299
Basic UDI-DI: 697444205SP001GG
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Intended purpose: Splint is used for transport the sick and wounded patients in hospitals, stadiums, ambulance equipment, disaster relief sites and military fields.

Declaration

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

Signature: Date:2025/8/21

Position: GM Place:Jiangsu/China