



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

**SUNGO Europe B.V.**  
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SRN: NL-AR-000000247

## Conformity Assessment

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

### Applicable Standards

EN ISO 14971:2019  
EN ISO 15223-1:2021  
EN ISO 20417:2021  
EN ISO 10993-1:2018  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013

## Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-RX-07.*

*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.*

## 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:** Vacuum Mattress Stretcher  
**Model:** YDC-6A1, YDC-6A3  
YDC6A4  
**EMDN:** V08050103  
**Basic UDI-DI:** 697444205612JS  
**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745  
**Intended purpose:** Vacuum Mattress Stretcher is used to transferring the wounded in hospitals, gymnasium, ambulance and station. This product is used for emergency rescue.

## 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: ZHOU JIAN PING  
Position: GM  
Place: Jiangsu /China  
Date:2023.11.30

