



# 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  
EN ISO 15223-1:2021  
EN ISO 20417:2021

### Remark

*The declaration of conformity is valid in connection with  
the release technical document CE/MDR-RX-02.  
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: Stair Stretcher  
Model: YDC-5L, YDC-5L01, YDC-5L02, YDC-5G,  
YDC-5M, YDC-5T1, YDC-5T2, YDC-5P, YDC-5R  
EMDN: V0805030101  
Basic UDI-DI: 697444205511JK  
Classification: Class I, According to Rule 1, Annex  
VIII, Regulation (EU) 2017/745

## 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 Jianping*

Position: GM

Date: 2023.11.20

Place: Jiangsu /China

