



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Olympisch Stadion 24, 1076DE  
Amsterdam, 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: 2016  
EN ISO 20417: 2021  
ISO 10993-1: 2018  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013  
EN 1865-1:2010+2010+A1:2015

## Remark

*The declaration of conformity is valid in connection with the release technical document CEMDR-CST-01.*

*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: Zhangjiagang Jiekang Medical Equipment Co., Ltd  
Address: Daxin Village, Daxin Town, Zhangjiagang City, Jiangsu Province, China

## Product Information

Name: Stretcher  
Model: See Annex  
GMDN: 35892  
Basic UDI-DI: /  
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: 

Date: 2021.08.24

Position: GM

Place: Zhangjiagang/China



## Annex

Product Name	Model	GMDN	Basic UDI-DI
Stretcher	YJK-F1, YJK-F2, YJK-F3, YJK-F4, YJK-F5, YJK-F6, YJK-F8, YJK-F9, YJK-F10, YJK-F13, YJK-14, YJK-FN1, YJK-CPR-1, YJK-CPR-2, YJK-CPR-3, YJK-A1-1, YJK-A3-1, YJK-A5-1, YJK-A6-1, YJK-B1-1, YJK-B2-1, YJK-B3-1, YJK-C-1, YJK-D-1, YJK-DL-1, YJK-E-1, YJK-EL-1, YJK-F1-1, YJK-F2-1, YJK-F3-1, YJK-F4-1, YJK-G-1, YJK-GL-1, YJK-H-1, YJK-HB-1, YJK-L-1, YJK-M-1, YJK-N-1, YJK-A-2, YJK-A-2-NM, YJK-A-3, YJK-A2-3, YJK-A3-3, YJK-A5-3, YJK-B-2, YJK-B-3, YJK-B2-3, YJK-B3-3, YJK-C-2, YJK-C-3, YJK-D-3, YJK-F-3, YJK-D2-3, YJK-E-3, YJK-G-3, YJK-L-2, YJK-L-3, YJK-L-3-NM, YJK-A-4, YJK-B-4, YJK-C-4, YJK-D-4, YJK-E-4, YJK-G-4, YJK-D2-4, YJK-A-5, YJK-B-5, YJK-C-5, YJK-D-5, YJK-E-5, YJK-E2-5, YJK-E3-5, YJK-A-6, YJK-B-6, YJK-C-6, YJK-D-6, YJK-A-7, YJK-C-7, YJK-B-A-7, YJK-E-7, YJK-E-7-2, YJK-E-7-3, YJK-E-7-4, YJK-E-7-5, YJK-E-7-6, YJK-H-7, YJK-H-8, YJK-H-9, YJK-N-7, YJK-A-8, YJK-A2-8, YJK-A3-8, YJK-B-8, YJK-B-9, YJK-16, YJK-16-1, YJK-16-2, YJK-17, YJK-18, YJK-19, YJK-20, YJK-9, YJK-7, YJK-6, YJK-WS-1, YJK-YW-01, YJK-YW-02, YJK-YL01, YJK-YL02, YJK-YL03, YJK-YL04, YJK-I-9	35597	/