



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Fascinatio Boulevard 522, Unit 1.7,  
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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  
EN ISO 10993-1: 2020  
EN ISO 10993-5: 2009  
EN 12182: 2012

## Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-HY-01-01.*

*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: YINGKOU HENYI FLOW CONTROL INC  
Address: Street No.B-9-1, Xilanqi, Hongqi Town ,  
Bayuquan District , Yingkou , Liaoning province,  
CHINA  
SRN: CN-MF-000009000

## Product Information

Name: Standing Transfer Platform, Manual  
Model: PR31PT002;PR31PT006;PR31PT007  
GMDN: 37953

**Intended Purpose Statement :** The Patient Transfer Aid helps a carer or attendant to assist a patient or user stand and transfer to another seat, bed, wheelchair, toilet or commode by standing and turning.

**Basic UDI-DI: 697463134PR31PTMC**

**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

## Declaration

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

Signature:  Date: May 8<sup>th</sup>, 2023

Position: GM

Place: Liaoning/China