



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

**Name:** SUNGO Europe B.V.  
**Address:** 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 20417:2021  
EN ISO 15223-1:2021  
EN ISO 10993-1:2020  
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-T0299-01.*  
*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:** Changzhou Newrise Medical & Hygiene Products Co., Ltd  
**Address:** No.39 Chuangye Road, Zhulin Town, Jintan District, Changzhou City, Jiangsu, China 213241  
**SRN:** CN-MF-000013196

## Product Information

**Name:** Disposable bib  
**Model:** 23\*35cm, 30\*40cm, 38\*50cm, 40\*60cm, 48\*58cm, 36\*64+10cm, 36\*66+10cm, 37\*50+10cm, 37\*64+10cm, 37\*65+10cm, 37\*66+10cm, 38\*65+10cm 38\*70+10cm, 40\*60+10cm, 45\*60+10cm  
**GMDN:** 61050  
**EMDN:** T0299  
**Basic UDI-DI:** 697632566BIBSV  
**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: Oct 8, 2022

Position: GM

Place: Changzhou/China

