



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

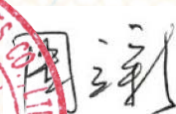
EMDN: T0299

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

