



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 15223-1: 2021

EN ISO 20417:2021

EN ISO 10993-1: 2020

EN ISO 10993-5: 2009

EN ISO 10993-10: 2023

EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-T040102-02.

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: 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: Reusable Incontinence Pad

Model : 40x50cm, 45x45cm, 45x60cm, 50x50cm, 50x60cm, 51x56cm, 53x56cm, 45X61cm, 75x90cm, 76x86cm, 80x90cm, 85x90cm, 85x135cm, 86x91cm, 86x132cm, 86x138cm, 86x96cm, 90x132cm, 90x140cm, 90x120cm, 90x150cm, 90x180cm, 91x91cm, 91x138cm, 91x142cm, 91x152cm, 91x182cm, 100x140cm, 110x130cm, 111x132cm

EMDN: T040102

Basic UDI-DI: 697632566INCPADSW

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: [Signature]

Position: GM

Date: April 2, 2024

Place: Changzhou/China