



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

**SUNGO Europe B.V.**

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: 2013

### Remark

*The declaration of conformity is valid in connection  
with the release technical document CE/MDR-  
T04010101-03*

*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:** KIMLEAD HYGIENE PRODUCTS (HEBEI)  
CO.,LTD.

**Address:** North of Dili Village, Hequ Town, Ningjin  
County, Xingtai, Hebei, China

**SRN: CN-MF-000025989**

## Product Information

**Name:** Medical Underpad

**Model:** Type II (Wood fluff pulp type)

**GMDN:** 61850

**EMDN:** T04010101

**Basic UDI-DI:** 697535962HLD001LV

**Classification:** Class I, According to Rule 5, 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: 2024.5.6

Position: General Manager

Place: Xingtai City



Basic UDI-DI	Model/Specification	UDI -DI
697535962HLD001LV	Type II (Wood fluff pulp type) / XXS	06975359620299
	Type II (Wood fluff pulp type) / XS	06975359620305
	Type II (Wood fluff pulp type) / S	06975359620312
	Type II (Wood fluff pulp type) / M	06975359620329
	Type II (Wood fluff pulp type) / L	06975359620336
	Type II (Wood fluff pulp type) / XL	06975359620343
	Type II (Wood fluff pulp type) / XXL	06975359620350
	Type II (Wood fluff pulp type) / XXXL	06975359620367
	Type II (Wood fluff pulp type) / XXXXL	06975359620374
	Type II (Wood fluff pulp type) / XXXXXL	06975359620381
	Type II (Wood fluff pulp type) / XXXXXXL	06975359620398
	Type II (Wood fluff pulp type) / 560*560	06975359620404
	Type II (Wood fluff pulp type) / 250*350	06975359620411
	Type II (Wood fluff pulp type) / 350*450	06975359620428
	Type II (Wood fluff pulp type) / 450*600	06975359620435
	Type II (Wood fluff pulp type) / 560*1200	06975359620442
	Type II (Wood fluff pulp type) / 600*900	06975359620459
	Type II (Wood fluff pulp type) / 800*800	06975359620466
	Type II (Wood fluff pulp type) / 900*900	06975359620473
	Type II (Wood fluff pulp type) / 800*1200	06975359620480
Type II (Wood fluff pulp type) / 600*1200	06975359620497	

697535962HLD001LV

Type II (Wood fluff pulp type) / 800*860	06975359620558
Type II (Wood fluff pulp type) / 210*500	06975359620565
Type II (Wood fluff pulp type) / 170*350	06975359620572
Type II (Wood fluff pulp type) / 302*350	06975359620589
Type II (Wood fluff pulp type) / 500*700	06975359620596
Type II (Wood fluff pulp type) / 550*600	06975359620602
Type II (Wood fluff pulp type) / 400*100	06975359620619
Type II (Wood fluff pulp type) / 420*180	06975359620626
Type II (Wood fluff pulp type) / 360*180	06975359620633
Type II (Wood fluff pulp type) / 500*190	06975359620640
Type II (Wood fluff pulp type) / 700*350	06975359620657
Type II (Wood fluff pulp type) / 600*350	06975359620664
Type II (Wood fluff pulp type) / 840*350	06975359620671
Type II (Wood fluff pulp type) / 800*900	06975359620688
Type II (Wood fluff pulp type) / 450*450	06975359620695
Type II (Wood fluff pulp type) / 600*600	06975359620701
Type II (Wood fluff pulp type) / 600*760	06975359620718
Type II (Wood fluff pulp type) / 800*900	06975359620725
Type II (Wood fluff pulp type) / 900*1200	06975359620732
Type II (Wood fluff pulp type) / 800*1600	06975359620749
Type II (Wood fluff pulp type) / 1000*2100	06975359620756

697535962HLD001LV	Type II (Wood fluff pulp type) / 180*1800	06975359620893
	Type II (Wood fluff pulp type) / 800*1800	06975359620923



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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: 2013

### Remark

The declaration of conformity is valid in connection with  
the release technical document CE/MDR- Y0999-01

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: KIMLEAD HYGIENE PRODUCTS (HEBEI)  
CO.,LTD.

Address: North of Dili Village, Hequ Town, Ningjin  
County, Xingtai, Hebei, China

SRN:CN-MF-000025989

## Product Information

Name: Adult Diaper

Model: Type II (Wood fluff pulp type)

GMDN: 11239

EMDN: Y0999

Basic UDI-DI: 697535962ZNK001WE

Classification: Class I, According to Rule 5, 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:

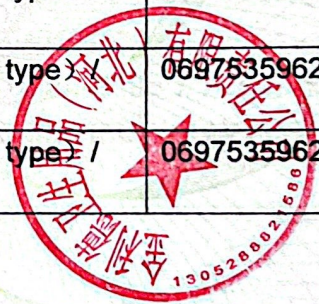
Date: April 19, 2022

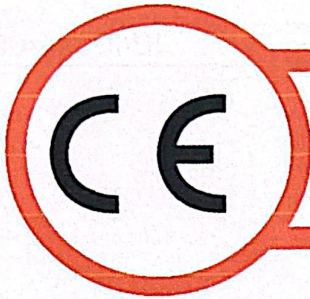
Position: General Manager

Place: Xingtai City



Basic UDI-DI	Model/Specification	UDI -DI
697535962ZNK001WE	Type II (Wood fluff pulp type) / 650*800	06975359620091
	Type II (Wood fluff pulp type) / 750*900	06975359620107
	Type II (Wood fluff pulp type) / 800*900	06975359620114
	Type II (Wood fluff pulp type) / 1000*1200	06975359620121
	Type II (Wood fluff pulp type) / XS	06975359620138
	Type II (Wood fluff pulp type) / S	06975359620145
	Type II (Wood fluff pulp type) / M	06975359620152
	Type II (Wood fluff pulp type) / L	06975359620169
	Type II (Wood fluff pulp type) / XL	06975359620176
	Type II (Wood fluff pulp type) / XXL	06975359620183
	Type II (Wood fluff pulp type) / XXXL	06975359620190
	Type II (Wood fluff pulp type) / XXXXL	06975359620206
	Type II (Wood fluff pulp type) / XXXXXL	06975359620213
	Type II (Wood fluff pulp type) / XXXXXXL	06975359620220





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**Applicable Standards**

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- EN ISO 20417: 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- T04010103-02. 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:** KIMLEAD HYGIENE PRODUCTS (HEBEI) CO.,LTD.

**Address:** North of Dili Village, Hequ Town, Ningjin County, Xingtai, Hebei, China

**SRN:** CN-MF-000025989

## Product Information

**Name:** Adult pull up diaper

**Model Type:** II (Wood fluff pulp type)

**GMDN:** 11239

**EMDN:** T04010103

**Classification:** Class I, According to Rule 5, 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:

Position: General Manager

Date: 2023.9.11

Place: Xingtai City



Basic UDI-DI	Model/Specification	UDI -DI
697535962LLK001Q2	Type II (Wood fluff pulp type) / 720*590	06975359620015
	Type II (Wood fluff pulp type) / 800*690	06975359620022
	Type II (Wood fluff pulp type) / 800*800	06975359620039
	Type II (Wood fluff pulp type) / 850*850	06975359620046
	Type II (Wood fluff pulp type) / XS	06975359620237
	Type II (Wood fluff pulp type) / S	06975359620244
	Type II (Wood fluff pulp type) / M	06975359620053
	Type II (Wood fluff pulp type) / L	06975359620060
	Type II (Wood fluff pulp type) / XL	06975359620077
	Type II (Wood fluff pulp type) / XXL	06975359620084
	Type II (Wood fluff pulp type) / XXXL	06975359620251
	Type II (Wood fluff pulp type) / XXXXL	06975359620268
	Type II (Wood fluff pulp type) / XXXXXL	06975359620275
	Type II (Wood fluff pulp type) / XXXXXXL	06975359620282

