



DECLARATION OF CONFORMITY

ACCORDING TO 2017/745/EU MEDICAL DEVICE REGULATION

EU REPRESENTATIVE

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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-LC-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.

Intended Use

The Adult Diaper is composed of absorbent material and worn between the legs used to collect urine and feces from an incontinent adult patient. The product is for single use only, and provided non-sterile.

Manufacturer

Name: Fujian Putian Licheng Paper Industry Co., Ltd.
Address: Jiaoxi Industry Huating Town, Chengxiang District, Putian City, Fujian, China
SRN: CN-MF-000008697

PRODUCT INFORMATION

NAME: Adult Diapers

Specification: Length: 70cm to 103cm, Width: 50cm to 90cm

GMDN: 11239

Basic UDI: 69235093AdultDiaper2C

Classification: Class I

Declaration

We herewith declare that the above-mentioned products meet the requirements of 2017/745/EU and the applicable standards above.

Signature:

Date:

Position: GM

Place: Fujian



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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-LC-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.

Intended Use

Adult Pants Diaper is a disposable undergarment composed of absorbent material intended to be worn around the perineum between the legs to collect urine and feces for disposal. The product is for

Manufacturer

Name: Fujian Putian Licheng Paper Industry Co., Ltd.
Address: Jiaoxi Industry Huating Town, Chengxiang District, Putian City, Fujian, China
SRN: CN-MF-000008697

PRODUCT INFORMATION

NAME: Adult Pants Diaper

Specification: Length: 60cm to 110cm, Width: 50cm to 120cm

GMDN: 11239

Basic UDI: 69235093AdultPantsPU

Classification: Class I

Declaration

We herewith declare that the above-mentioned products meet the requirements of 2017/745/EU and the applicable standards above.

Signature:

Date:

Position: GM

Place: Fujian



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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-LC-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.

Intended Use

The Underpads are intended to be placed on a bed mattress surface and underneath a patient to absorb bodily fluids resulting from surgical procedures, childbirth and/or incontinence. The product is for single use only, and provided non-sterile.

Manufacturer

Name: Fujian Putian Licheng Paper Industry Co., Ltd.
Address: Jiaoxi Industry Huating Town, Chengxiang District, Putian City, Fujian, China
SRN: CN-MF-000008697

Product Information

Name: Underpad
Specification: Width: 30cm to 100cm, Length: 30cm to 230cm
GMDN: 61850
Basic UDI: 69235093UnderpadWH
Classification: Class I

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:

Position: GM

Place: Fujian



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-00000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
ISO 13485: 2016
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-T040102-01.

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.

Intended Purpose

A thin, anatomically shaped pad with high absorbency to collect urine and feces of an incontinent patient.

Manufacturer

Name: Fujian Putian Licheng Paper Industry Co., Ltd
Address: Jiaoxi Industry, Huating Town, Chengxiang District, Putian, Fujian, China
SRN: CN-MF-000008697

Product Information

Name: Shaped Pads

Model: Length: 25cm to 85cm, Width: 15cm to 40cm,
Customized
EMDN: T040102

Basic UDI-DI: 69235093ShapedPadsS7

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:

Position: GM

Place: Putian/China