



DECLARATION OF CONFORMITY

ACCORDING TO 2017/745/EU MEDICAL DEVICE REGULATION

EU REPRESENTATIVE

SUNGO Europe B.V.
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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-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, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

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

Signature:  Date: 2021.2.5.

Position: GM Place: Fujian

