CE

DECLARATION OF CONFORMITY

ACCORDING TO 2017/745/EU 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 15223-1:2016
EN 1041:2008+A1:2013
ISO 10993-1:2018
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

Incontinence briefs with high absorbency. For use in moderate to severe fecal and urinary incontinence.

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
Clasification: 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: 2025.2.6

Position: GM Place: Fujian