



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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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-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, 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: 黄丽梅

Date: 2025.2.5

Position: GM

Place: Fujian

