



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-T04010101-01.

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

Address: FEIXI HONGWEI MEDICAL DEVICES CO., LTD

Address: 2nd Floor, Building 6, Junction of Chuangxin Ave and Changgu Rd, Economic Development Zone, Feixi County, Hefei City, Anhui, China

SRN: CN-MF-000033411

Product Information

Name: DISPOSABLE MEDICAL UNDERPAD

Model: Disposable Underpad, Disposable Bed Liner, Urine Pad, Nursing Pad, Adult Care Mat, Incontinence Bed Pads, Incontinence Guards, Underpads, Absorbent Underpad,

Disposable Pads, Disposable Bed Pads, Disposable Bed Mats, Disposable Diaper

GMDN: 61850

EMDN: T040102

Basic UDI-DI: 697491661UNDPUR

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:



Position: GM

Date:

2023.04.11

Place: Anhui/China