



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit
1.7, Capelle aan den IJssel, 2909VA, 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
ISO13485

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-FY-06.

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

Name: Xiantao Fortune Medical Supplies Co., Ltd
Address: No.2 Fuyuan Road, Pengchang Town,
Xiantao City, Hubei Province, China
SRN:CN-MF-000003236

Product Information

Name: Pillow Case
Model: 50*60cm/54*80cm/40*60cm/30*50cm
or customized
GMDN: 37456
Basic UDI-DI: 697439066fy-90984
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: 2024.08.14

Position: GM Place: Xiantao/China



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DECLARATION OF CONFORMITY

ACCORDING TO MEDICAL DEVICES ORDINANCE OF 1 JULY 2020

CH Representative

Name: SUNGO Technical Service GmbH
Address: Bahnhofstrasse 21,6300 Zug,
Switzerland
CHRN: CHRN-AR-20002937

Conformity Assessment

Conformity Assessment Procedure
Section 1, Chapter 3 of Medical Devices
Ordinance of 1 July 2020

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: 2023
EN ISO 10993-23: 2021

Remark

*The declaration of conformity is valid in connection
with the release technical document*

CH/MEDDO-FY-05

*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

Name: Xiantao Fortune Medical Supplies Co., Ltd
Address: No.182 Hechang New Street,
Pengchang Town, Xiantao City, Hubei Province,
China
SRN:CN-MF-000003236

Product Information

Name: Pillow case
Model: White, 60x60cm, PP25-30g/m²
EMDN: T030599
Classification:
Class I, According to Section2, Chapter2 of Medical
Devices Ordinance of 1 July 2020

Declaration

We herewith declare that the above-mentioned
products meet the requirements of Medical Devices
Ordinance of 1 July 2020 and the applicable
standards above.

Signature: 

Date: 2024. 8. 22

Position: GM

Place: Xiantao/China

