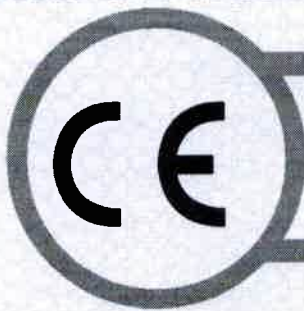




DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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-07.

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 : Tangas
Ttem number:253-11
Model : 140*60cm/53*32cm/110*35cm/48*38cm/
60*85cm/56*35cm or customized
GMDN : 41588
Basic UDI-DI : 697439066fy-8087V
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.

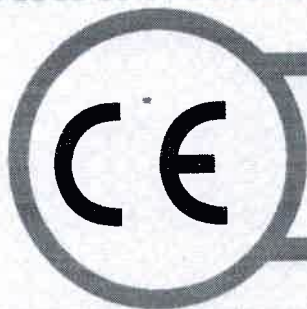
Signature: 

Date: 2022.01.11

Position: GM

Place: Xiantao/China





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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-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.*

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 : Bed Sheet
Item number:09173
Model :
190*90cm,200*100cm,220*120cm,240*140cm,80*210cm,
85*210cm,95*210cm,100*210cm or customized
GMDN : 47456
Basic UDI-DI : 697439066fy-4046Z
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.

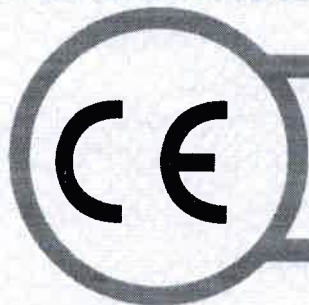
Signature: 

Date: 2022.01.11

Position: GM

Place: Xiantao/China





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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-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

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 : Diadem
Item number: 270-11
Model : customized
GMDN : 32297
Basic UDI-DI : 697439066fy-3036Q
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.

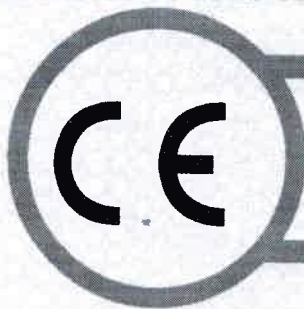
Signature: 

Date: 2022. 01. 11

Position: GM

Place: Xiantao/China





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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-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.

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 : Slips
Item number:09175
Model : 15*40cm,16*40cm,17*40cm or Customized
GMDN : 15056
Basic UDI-DI : 697439066fy-50578
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: 2022.01.11

Position: GM

Place: Xiantao/China

