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

Manufacturer

Name: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
ISO 15223-1:2021/Amd 1:2025
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Product Information

Name: Absorbent cotton wool
Model: Specification: 0.1g-9.9g (every 0.1g for a specification), 10g-999g (every 1g for a specification, 1kg-50kg (every 50g for a specification)
EMDN: M020199
Basic UDI-DI: 697033651acw0012G
Classification: Class I, According to Rule 4, 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:Wu Anhong Date: 2025-04-03

Position: GM Place: Lianyungang/ China

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-M020199-01.

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.

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

Manufacturer

Name: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
ISO 15223-1:2021/Amd 1:2025
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Product Information

Name: Cotton Roll
Model: Specification: 0.1g-9.9g (every 0.1g for a specification), 10g-999g (every 1g for a specification, 1kg-50kg (every 50g for a specification)
EMDN: M020199
Basic UDI-DI: 697033651cr001QH
Classification: Class I, According to Rule 4, Annex VIII, Regulation (EU) 2017/745

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-M020199-02.
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.

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:Wu Anhong Date: 2025-04-03

LIANYUNGANG BAISHUN MEDICAL TREATMENT ARTICLES CO.,LTD 连云港百顺医疗用品有限公司

Position: GM Place: Lianyungang/ China

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

Manufacturer

Name: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
ISO 15223-1:2021/Amd 1:2025
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Product Information

Name: Dental Cotton roll
Model: Specification: Size of Diameter: 3mm-50mm (every 1mm for a specification)
Size of length: 8mm-200mm (every 1mm for a specification); 200mm-1000mm (every 10mm for a specification)
EMDN: Q019004
Basic UDI-DI: 697033651dcr0012L
Classification: Class I, According to Rule 5, 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: Wu Anhong Date: 2025-04-03

Position: GM Place: Lianyungang/China

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Q019004-03.
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.

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

Manufacturer

Name: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
ISO 15223-1:2021/Amd 1:2025
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Product Information

Name: Cotton Ball
Model: Specification：Size of Diameter: 0.1mm-150mm (every 0.1mm for a specification) or Size of grammage：0.1g-10g(every 0.1g for a specification)
Package：0.1-4.9g (every 0.1g for a specification)，5g-999g (every 1g for a specification), 1kg-50kg (every 50g for a specification)
EMDN: M020199
Basic UDI-DI: 697033651cb001LZ
Classification: Class I, According to Rule 4, 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:Wu Anhong Date: 2025-04-03

Position: GM Place: Lianyungang/ China

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-M020199-04.

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.

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
ISO 15223-1:2021/Amd 1:2025
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 CE/MDR-M020199-05.

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: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Product Information

Name: Absorbent Gauze Zigzag
Model: Cotton Yarn:40*40, 32*32, 21*21, 32*21, 16*16, With or without X-ray detectable thread (or tape)
Mesh: 11thr, 12thr, 13thr, 15thr, 17thr, 18thr, 20thr, 22thr, 24a thr, 24b thr, 24c thr, 21c thr, 24thr, 27.5thr
Width:45cm, 60cm, 75cm, 80cm, 90cm, 100cm, 110cm, 115cm, 120cm, 125cm, 130cm, 135cm, 150cm, 160cm, 36inch,
Length:100yard, 91m,100m, 1000m, 2000m, 3000m, 4000m, 5000m
Packing: 1roll/bag, Paper/PE bag
Thickness:1ply, 2ply,4ply
EMDN: M020199
Basic UDI-DI: 697033651agz0014H
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:Wu Anhong Date: 2025-04-03

LIANYUNGANG BAISHUN MEDICAL TREATMENT ARTICLES CO.,LTD 连云港百顺医疗用品有限公司

Position: GM Place: Lianyungang/ China

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
ISO 15223-1:2021/Amd 1:2025
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 CE/MDR-M020199-06.

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: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Product Information

Name: Gauze Swab
MODEL: Cotton Yarn: 40*40, 32*32, 21*21, 32*21, 16*16, With or without X-ray detectable thread (or tape)
Mesh: 11thr, 12thr, 13thr, 15thr, 17thr, 18thr, 20thr, 22thr, 24a thr, 24b thr, 24c thr, 21c thr, 24thr, 27.5thr
Size: 4cm×6cm, 5cm×5cm, 5cm×7cm, 5cm×7.5cm, 6cm×7cm, 6cm×8cm, 7cm×8cm, 7.5cm×7.5cm, 7.5cm×10cm, 8cm×8cm, 8cm×10cm, 9cm×11cm, 10cm×10cm, 10cm×12cm, 10cm×15cm, 10cm×20cm, 10cm×40cm, 20cm×40cm, 11cm×17cm, 12cm×12cm, 14cm×14cm, 15cm×15cm, 16cm×16cm, 20cm×20cm
Packing: 50pcs/bag;100pcs/bag; 200pcs/bag; 500pcs/bag; Paper bag/paper-plastic bag
Thickness: 4ply, 6ply, 8ply, 12ply, 16ply, 24ply, 32ply
EMDN: M020199
Basic UDI-DI: 697033651gs001S4
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: Wu Anhong Date: 2025-04-03

LIANYUNGANG BAISHUN MEDICAL TREATMENT ARTICLES CO.,LTD 连云港百顺医疗用品有限公司

Position: GM Place: Lianyungang/ China

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
ISO 15223-1:2021/Amd 1:2025
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 CE/MDR-M040503-07.

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: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Product Information

Name: Lap Sponge
Model: Cotton Yarn:40*40, 32*32, 21*21, 32*21, 16*16, With or without X-ray detectable thread (or tape)
Mesh: 11thr, 12thr, 13thr, 15thr, 17thr, 18thr, 20thr, 22thr, 24a thr, 24b thr, 24c thr, 21c thr, 24thr, 27.5thr
Size:20cmx20cm, 22.5cmx22.5cm, 25cmx25cm, 30cmx30cm, 40cmx40cm, 40cmx45cm, 45cmx45cm, 50cmx50cm, 50cmx70cm
Packing:5/10/25/50/100pcs per pack
Thickness:4ply, 6ply, 8ply, 12ply, 16ply, 24ply
EMDN: M040503
Basic UDI-DI: 697033651ls001TT
Classification: Class I, According to Rule 4, 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: Wu Anhong Date: 2025-04-03

LIANYUNGANG BAISHUN MEDICAL TREATMENT ARTICLES CO.,LTD 连云港市百顺医疗用品有限公司

Position: GM Place: Lianyungang/ China

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
ISO 15223-1:2021/Amd 1:2025
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 CE/MDR-M020199-08.

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: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Product Information

Name: Gauze Roll
Model: Cotton Yarn:40*40, 32*32, 21*21, 32*21, 16*16, With or without X-ray detectable thread (or tape)
Mesh: 11thr, 12thr, 13thr, 15thr, 17thr, 18thr, 20thr, 22thr, 24a thr, 24b thr, 24c thr, 21c thr, 24thr, 27.5thr
Width:45cm, 60cm, 75cm, 80cm, 90cm, 100cm, 110cm, 115cm, 120cm, 125cm, 130cm, 135cm, 150cm, 160cm, 36inch,
Length:100yard, 91m, 100m, 1000m, 2000m, 3000m, 4000m, 5000m
Packing: 1roll/bag, Paper/PE bag
Thickness:1ply, 2ply, 4ply
EMDN: M020199
Basic UDI-DI: 697033651gr001RV
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: Wu Anhong Date: 2025-04-03

Position: GM Place: Lianyungang/ China

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
ISO 15223-1:2021/Amd 1:2025
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 CE/MDR-M020199-09.

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: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Product Information

Name: Zigzag Gauze
Model: Cotton
Yarn:40*40,32*32,21*21,32*21,16*16,With or without X-ray detectable thread (or tape)
Mesh: 11thr,12thr,13thr,15thr,17thr,18thr,20thr,22thr,24a thr,24b thr,24c thr,21c thr,24thr,27.5thr
Size: 5*5cm, 7.5*7.5cm , 10*10cm, 10*20cm, 20*20cm, 0.65*5m/pc;
Packing: 20pcs/bag, 50pcs/bag,100pcs/bag, Paper bag/paper-plastic bag
Thickness:4ply, 8ply, 12ply, 24ply, 32ply
EMDN: M020199
Basic UDI-DI: 697033651zg001VZ
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:Wu Anhong Date: 2025-04-03

LIANYUNGANG BAISHUN MEDICAL TREATMENT ARTICLES CO.,LTD 连云港市百顺医疗用品有限公司

Position: GM Place: Lianyungang/ China

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
ISO 15223-1:2021/Amd 1:2025
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 CE/MDR-M03030199-10.

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: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Product Information

Name: Medical bandage
Model: Cotton
Yarn:40*40,32*32,21*21,32*21,16*16,With or without X-ray detectable thread (or tape)
Mesh:
11thr,12thr,13thr,15thr,17thr,18thr,20thr,22thr,24a thr,24b thr,24c thr,21c thr,24thr,27.5thr
Width-4.5cm,5cm,7.5cm,8cm,10cm,12cm15cm,20cm;
Length-4m,4.5m,5m,9.1m,10m
Packing: 1roll/bag, 12rolls/bag, Paper bag/paper-plastic bag
Thickness:4ply, 8ply, 12ply, 24ply, 32ply
EMDN: M03030199
Basic UDI-DI: 697033651mb001QF
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: Wu Anhong Date: 2025-04-03

LIANYUNGANG BAISHUN MEDICAL TREATMENT ARTICLES CO.,LTD 连云港市百顺医疗用品有限公司

Position: GM Place: Lianyungang/ China

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
ISO 15223-1:2021/Amd 1:2025
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 CE/MDR-M03030199-11.

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: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Product Information

Name: Adhesive Wound Dressing
Model: 5x5cm, 6x6cm, 8x8cm, 8x6cm, 10x5cm, 10x10cm, 10x15cm, 10x20cm, 10x25cm,10x30cm,10x35cm
EMDN: M03030199
Basic UDI-DI: 697033651awd00157
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: Wu Anhong Date: 2025-04-03

Position: GM Place: Lianyungang/ China

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
ISO 15223-1:2021/Amd 1:2025
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN 14683: 2025

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-T020699-12.

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: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Product Information

Name: Disposable Face Mask
Model: Flat-type
EMDN: T020699
Basic UDI-DI: 697033651dfm0012J
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: Wu Anhong Date: 2025-04-03

LIANYUNGANG BAISHUN MEDICAL TREATMENT ARTICLES CO.,LTD 连云港市百顺医疗用品有限公司

Position: GM Place: Lianyungang/ China

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
ISO 15223-1:2021/Amd 1:2025
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 CE/MDR-M03030199-13.

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: Lianyungang baishun medical treatment articles co.,ltd
Address: Bailu street, bailu town, guannan district, lianyungang city, jiangsu province, China
SRN: CN-MF-000010197

Product Information

Name: Zinc Oxide Tape
Model: 2.5cmX3M, 2.5cmX4M, 2.5cmX5M, 2.5cmX3Y, 2.5cmX4Y, 2.5cmX5Y, 5cmX3M, 5cmX4M, 5cmX5M, 5cmX3Y, 5cmX4Y, 5cmX5Y, 7.5cmX3M, 7.5cmX4M, 7.5cmX5M, 7.5cmX3Y, 7.5cmX4Y, 7.5cmX5Y, 10cmX3M, 10cmX4M, 10cmX5M, 10cmX3Y, 10cmX4Y, 10cmX5Y, 15cmX3M, 15cmX4M, 15cmX5M, 15cmX3Y, 15cmX4Y, 15cmX5Y, 20cmX3M
EMDN: M03030199
Basic UDI-DI: 697033651zot001G4
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: Wu Anhong Date: 2025-04-03

LIANYUNGANG BAISHUN MEDICAL TREATMENT ARTICLES CO.,LTD 连云港市白顺医疗用品有限公司

Position: GM Place: Lianyungang/ China

Lianyungang Baishun Medical Treatment Articles Co.,Ltd

Certificate of Analysis

Product item	GAUZE ROLL	Product lot No.	24204513
Describe	90CM*100M	Tex.date	05-2025
MFG.date	05-2025	EXP.date	05-2030
Name	**Gauze Roll**		

Item	Unit	Standard(EP93)	Test result	Conclusion
loss on drying	%	≤8	2,1%	Ok
sinking time	S	≤10	6S	ok
fluorescence		No	No	ok
acidity alkalinity	PH	7±0.5	7.1	ok
whiteness	Pete	≥80	81.3	ok
water soluble substance	%	≤0.50	0.18%	ok
ether soluble substance	%	≤0.50	0.21%	ok
easily oxidized	m	≥5	20min	ok
sulphated ash	%	≤0.50	0.26%	ok
color substance		No	No	ok
foreing fibers		No	No	ok
Fiber	um	10-40	15um	
conclusion	Conform to the standard (EP93)			

MANUFACTURER'S DECLARATION

Product identification, intended use and absence of a separate IFU

We, Lianyungang Baishun Medical Treatment Articles Co., Ltd., at Bailu Street, Bailu Town, Guannan District, Lianyungang City, Jiangsu Province, China, SRN CN-MF-000010197, as the manufacturer, declare under our sole responsibility:

Product / brand	Absorbent gauze roll / I&A MEDICAL
Presentation	90 cm × 100 m; 4-ply; one roll individually wrapped in paper
Classification / condition	Class I medical device; non-sterile; single use
UDI-DI	**06970336510082**
Basic UDI-DI	**697033651gr001RV**
Importer in Spain	GRUPO TRISTAN GLOBAL I&A, S.L.

1. Product identification and intended use

The UDI-DI above corresponds specifically to the 90 cm × 100 m, 4-ply gauze rolls supplied under the I&A MEDICAL brand.

The product is intended for medical and healthcare use in external care, for fluid absorption and protection as a secondary dressing, in applications that do not require sterile material.

2. Absence of separate instructions for use (IFU)

The product is supplied without a separate IFU. Annex I, Section 23.1(d), of Regulation (EU) 2017/745 permits Class I and IIa devices to be supplied without IFU when safe use without such instructions is possible, unless another provision of Section 23 requires otherwise.

For this product, the manufacturer determines that its simple intended use can be performed safely by the intended users without a separate IFU. It requires no installation, calibration or programming, and no sterilisation before its intended non-sterile use. This determination is supported by the manufacturer's technical documentation and risk assessment.

3. Information accompanying the product

Product identification, storage information and precautions are communicated through the label and packaging. The manufacturer remains responsible for the applicable information and labelling requirements under Article 10(11) and Annex I, Sections 23.1 and 23.2, including Spanish-language information for Spain.

Information on the risks of reuse and safe disposal is available to users upon request under Annex I, Sections 23.4(p) and 23.4(v).

Issued for the importer's product documentation, AEMPS–RECOPS notification and customer information.

For and on behalf of the manufacturer

Name and position: _____

Place and date: Jiangsu, China 2026-11-5

Signature and company stamp:

DECLARACIÓN DEL FABRICANTE

Identificación, uso previsto y ausencia de IFU independiente

Lianyungang Baishun Medical Treatment Articles Co., Ltd., con domicilio en Bailu Street, Bailu Town, Guannan District, Lianyungang City, Jiangsu Province, China, SRN CN-MF-000010197, como fabricante, declara bajo su exclusiva responsabilidad:

Producto / marca	Rollo de gasa absorbente / I&A MEDICAL
Presentación	90 cm × 100 m; 4 capas; un rollo envuelto individualmente en papel
Clasificación / condición	Producto sanitario clase I; no estéril; de un solo uso
UDI-DI	**06970336510082**
Basic UDI-DI	**697033651gr001RV**
Importador en España	GRUPO TRISTAN GLOBAL I&A, S.L.

1. Identificación del producto y uso previsto

El UDI-DI anterior corresponde específicamente a los rollos de gasa de 90 cm × 100 m, 4 capas, suministrados bajo la marca I&A MEDICAL.

El producto está destinado al uso médico y sanitario en curas externas, para la absorción de fluidos y la protección como apósito secundario, en aplicaciones que no requieran material estéril.

2. Ausencia de instrucciones de uso (IFU) independientes

El producto se suministra sin IFU independiente. El anexo I, apartado 23.1.d), del Reglamento (UE) 2017/745 permite prescindir de IFU en productos de clase I y IIa cuando puedan utilizarse de forma segura sin ellas, salvo que otra disposición del apartado 23 las exija.

Para este producto, el fabricante determina que su uso previsto sencillo puede realizarse de forma segura por los usuarios previstos sin IFU independiente. No requiere instalación, calibración ni programación, ni esterilización previa para su uso no estéril previsto. Esta determinación se sustenta en la documentación técnica y la evaluación de riesgos del fabricante.

3. Información que acompaña al producto

La identificación, la conservación y las precauciones se comunican mediante el etiquetado y el envase. El fabricante mantiene su responsabilidad sobre la información y el etiquetado exigibles conforme al artículo 10.11 y al anexo I, apartados 23.1 y 23.2, incluida la información en español para España.

La información sobre los riesgos de reutilización y la eliminación segura se facilita al usuario previa solicitud, conforme al anexo I, apartados 23.4.p) y 23.4.v).

Se emite para la documentación del importador, la comunicación en AEMPS–RECOPS y la información a clientes.

Por y en nombre del fabricante

Nombre y cargo: _____

Lugar y fecha: _____Jiangsu, China 2025-11-5_____

Firma y sello de la empresa:



29-Dec-23

HUACTEST
华才检测

FDA REGISTRATION CONFIRMATION

Thank you for appointing Frosa Technology LLC as your U.S. Agent, we hereby state that we accepts the appointment to be the U.S. Agent for your Medical Device Facility, and we have completed the registration activation confirmation for the FDA Medical Device Registration and Listing Module with the US Food & Drug Administration for the Year 2024 of

Lianyungang Baishun Medical Treatment Articles Co.,Ltd

Bailu Town, Guannan District
Lianyungang, Jiangsu CN 222000

The Registration information is as below:

Owner/Operator Number	**10050177**
Establishment Registration Number	**3012430313**

listing No	Product name	Product code	Activites
View attachments 1			

Please inform us of any changes to:
the company information
additional product categories or additional products
discontinuation of product categories or products

we strongly recommend you to contact us via email U.S.agent@frosatechnology.com to update the information.If you have any queries regarding regulation, please do not hesitate to contact us.

Yours sincerely,

HUACTEST
华才检测

Attachments 1

listing No	Classification Name＆Product name	Product code	Activites
D250850	Cotton, Roll - Cotton Pad, Cotton Sliver, Absorbent Cotton Wool, Bleached Cotton, Cosmetic Cotton; Cotton Roll, Zigzag Cotton, Dental Cotton Roll, Cotton Ball, Cotton With Nonwoven, Cotton With Gauze, Cotton Slices	EFN	Manufacturer
D250852	Gauze / Sponge,Nonresorbable For External Use - Gauze, Gauze Swabs, Gauze Bandage, Gauze Roll, Lap Sponge, Gauze Zigzag, Gauze Ball, Non Woven Swabs, Cotton Swabs	NAB	Manufacturer
D365658	Mask, Scavenging - Disposable Face Mask	KHA	Manufacturer
D250854	Applicator, Absorbent Tipped, Non-Sterile - Cotton Bud	KXF	Manufacturer
D250853	Bandage, Elastic - Bandage, Cohesive Bandages, High Elastic Bandage, Crepe Bandages, Adhesive Bandages,; Plaster Of Paris Bandages, First Aid Bandage, Triangular Bandage, PBT Bandage	FQM	Manufacturer
D476895	Bandage, Cast - Cast Padding	ITG	Manufacturer
D365656	Fiber, Medical, Absorbent - Non Woven Swab	FRL	Manufacturer
D476896	Applicator, Absorbent Tipped, Sterile - Cotton Swabs	KXG	Manufacturer
D476894	Tape And Bandage, Adhesive - Kinesiology Tape, Non-Woven Tape, Elastic Tape, Kinesiology Tape; Tape, Zinc Oxide Tape, PE Tape, Silk Tape, Non-Woven Tape, Elastic Tape	KGX	Manufacturer
D365660	Cap, Surgical - Disposable Mob Cap	FYF	Manufacturer

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer R. Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M. Schmitz - Konte

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20203913

Bijlagen
-

Uw aanvraag
10 augustus 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 13 augustus 2020
Betreft: notificatie medische hulpmiddelen klasse I

Geachte heer Luo,

Hierbij bevestig ik de ontvangst op 10 augustus 2020 van de notificatie van de medische hulpmiddelen klasse I, die bedrijf Lianyungang Baishun Medical Treatment Articles CO., LTD, met Europees gemachtigde SUNGO Europe B.V. , als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen.
De producten zijn onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over een of meer van deze producten het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Lap Sponge
(geen merknaam) (NL-CA002-2020-52885)
Absorbent Cotton Wool
(geen merknaam) (NL-CA002-2020-52878)
Absorbent Gauze Zigzag
(geen merknaam) (NL-CA002-2020-52879)
Adhesive Wound Dressing
(geen merknaam) (NL-CA002-2020-52880)
cotton ball
(geen merknaam) (NL-CA002-2020-52881)
cotton roll
(geen merknaam) (NL-CA002-2020-52882)
Gauze Roll
(geen merknaam) (NL-CA002-2020-52884)
Gauze Swab
(geen merknaam) (NL-CA002-2020-52883)
Medical bandage
(geen merknaam) (NL-CA002-2020-52886)
Zigzag Gauze
(geen merknaam) (NL-CA002-2020-52887)
Zinc Oxide Tapes
(geen merknaam) (NL-CA002-2020-52888)

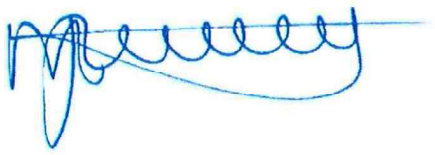
Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2]. Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw producten overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde geacht binnen achttien maanden bovenstaande hulpmiddelen te registreren in Eudamed.[3]

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van de bovengenoemde producten slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van de desbetreffende producten als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

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[1] O.g.v. art. 29 MDR.

[2] O.g.v. art. 31 MDR.

[3] www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf. Zie vraag en antwoord nummer 20.

FDA

Fiscal Year 2027

This is a notice to the establishment whose Facility Registration and Device Listing have been done within the Fiscal Year 2027.

Establishment information

Name: LIANYUNGANG BAISHUN MEDICAL TREATMENT ARTICLES CO., LTD

Address: No. 617, Bailu Village, Bailu Town, Guannan County, Lianyungang City, Jiangsu, 222000, CHINA

Inquiry Website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Facility Registration and Device Listing Information

Owner/Operator Number: 10096716

Registration Number:
You will receive another e-mail providing you with your registration number **in approximately 30 to 90 days**. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.

Listing No.	Product Code	Proper Name(s)	Registration Role
D613504	EFN	Cotton roll, Zigzag cotton, Dental cotton roll, Cotton ball, Cotton with nonwoven, Cotton with gauze, Cotton slices, Cotton pad, Cotton sliver, Absorbent Cotton Wool, Bleached cotton, Cosmetic cotton, Nose bleed cotton	Manufacturer
D613505	NAB	Gauze, Gauze swabs, Gauze bandage, Gauze roll, Lap sponge, Gauze zigzag, Gauze ball, Non woven swabs, Cotton swabs	
D613506	FQM	Bandage, Cohesive bandages, High elastic bandage, Crepe bandages, Adhesive bandages, Plaster of paris bandages, First aid bandage, Triangular bandage, PBT bandage; Tubular bandage	
D613507	KXF	Cotton bud	
D613508	FRL	Non woven swab	
D613509	LYU	Glove	
D613510	FYF	Disposable mob cap	

D613511	KGX	Kinesiology tape, Non-woven tape, Elastic tape, Kinesiology tape, Wound plaster	
D613512	ITG	Cast padding	
D613513	KXG	Cotton swabs	

Certificate of Registration

nqa.

兹证明

连云港市百顺医疗用品有限公司

统一社会信用代码：**91320724791064309D**

经营地址：**江苏省连云港市灌南县百禄镇百禄街**

注册地址：**灌南县百禄镇百禄街**

的质量管理体系适用于

非灭菌：脱脂棉及其产品（脱脂棉球、棉片、棉卷）、脱脂纱布绷带的生产和销售（许可资质范围内），脱脂棉条、折叠棉、牙科棉卷、医用脱脂纱布、纱布片、纱布卷、纱布棉垫、腹部垫、无纺布片的生产和销售（仅限出口）；凡士林纱布片、酒精棉片、弹性绷带、石膏绷带、三角绷带、氧化锌胶带、一次性使用医用口罩、一次性注射器、尿袋、导尿管、压舌板、棉签的销售（仅限出口）

已经NQA根据标准

ISO 13485:2016

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系，并由NQA进行监督。

获证组织必须定期接受监督审核并经审核合格，此证书方继续有效。

本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询

SNQA查询网站：www.snqa.com.cn

总 经 理

证书号：**131383**

初次发证日期：**2022年08月02日**

上一认证周期：**2025年08月02日**

本次审核日期：**2025年07月29日**

本次发证日期：**2025年08月06日**

证书有效期至：**2028年08月02日**

UKAS MANAGEMENT SYSTEMS

0015

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

使用UKAS认可标志表明对NQA所持有的编号为015的认可证书所涵盖的活动进行认可；
NQA是NQA认证有限公司的商业名称，注册号为09351758。 注册地址：Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, 英国；
证书为NQA所有，客户需在NQA要求时将证书返还；
上海恩可埃认证有限公司，地址：中国（上海）自由贸易试验区陆家嘴环路958号2201室。

Certificate of Registration

This is to certify that the Quality Management System of

Lianyungang Baishun Medical Treatment Articles Co., Ltd.

Unified Social Credit Code: **91320724791064309D**

Operation Address: **Bailu Street, Bailu Town, Guannan County, Lianyungang City, Jiangsu Province, China**

Registered Address: **Bailu Street, Bailu Town, Guannan County, Lianyungang City, Jiangsu Province, China**

applicable to

The Production and Sales of Non-Sterile: Absorbent Cotton and its Products(Absorbent Cotton Ball, *Cotton Pad, Cotton Roll*), *Absorbent Gauze Bandage(Within The Scope Of License Qualification)*; The Production and Sales of Cotton Coil, Zigzag Cotton, Dental Cotton Roll, Medical Absorbent Gauze, Gauze Swab, Gauze Roll, Gauze and Cotton Combined Dressing(Cotton Gauze Dressing), Lap Sponge, Non-Woven Swab(Export only); The Sales of Vaseline Gauze, Alcohol Prep Pad, Elastic Bandage, Plaster of Paris Bandage, Triangle Bandage, Zinc Oxide Adhesive Tape, Disposable Medical Mask, Disposable Syringe, Urine Bag, Foley Catheter, Tongue Depressor, Cotton Swab(Export only)

has been assessed and registered by NQA against the provisions of

ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number: **131383**

Issue Date: **02 August 2022**

Previous Certificate Expiry: **02 August 2025**

The Latest Audit Date: **29 July 2025**

Reissue Date: **06 August 2025**

Valid Until: **02 August 2028**

UKAS MANAGEMENT SYSTEMS

0015

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.
NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.
This certificate is the property of NQA and must be returned on request.
Shanghai NQA Certification Co., Ltd. Address: Room 2201, 958 Lujiazui Ring Road, China (Shanghai) Pilot Free Trade Zone.