

MAMELUCO CON CAPUCHA



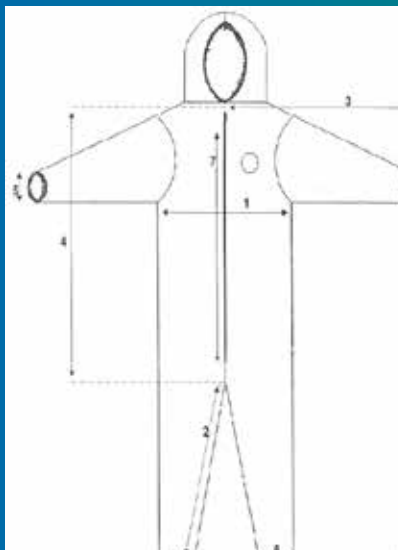
MAMELUCO CON CAPUCHA	
Nombre Comercial	Mamelucos
Marca o fabricante	Xian Tao Lijun
Procedencia	China
Modelo	U-PS7001
Talla	M,L,XL,2XL
Características Técnicas	Material microporoso Puño con elástico Con capucha sin bota Con solapa con cremallera Tobillos elásticos impermeables 63 gsm
Dimensiones y pesos cm y kg	56*36*42cm/12kg
Presentación del producto	50 piezas por caja
Certificaciones	FDA-CE

BENEFICIOS

- Mayor resistencia al desgarro.
- Vidación internacional.
- Calidad certificada y testeada.
- El modelo más versátil a nivel internacional.

APLICACIONES

- Procesos industriales con Ácido Sulfúrico Concentrado y/o Ácido Clohídrico.
- Industria petrolera en general.
- Minería de Plomo y Cobre.
- Especial para Laboratorios químicos y biológicos.
- Buen comportamiento en ambientes con grasas y aceites.
- Usos ilimitados en industrias, construcción, mantención, otras.
- No combustible, retardante al fuego.
- No usar ante fuego directo.



MEDIDAS

Unidad en cm		M	L	XL	XX
Pecho	1	61.5	63.5	67.3	69.8
Longitud de la entrepierna	2	70	70.5	71.5	73
Longitud de la manga superior	3	82.5	81.2	88	93
Longitud de la cremallera	4	93	98	100	107
Manga Cuff Rlxd / Extd	5	15.5	15.2	17.15	17.7
Ancho de la capucha	6	26	27.9	27.9	27.9



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

**XIANTAO LIJUN NON-WOVEN PRODUCTS CO.,LTD
NO.138 QIANQIU SOUTH STREET, PENGCHANG TOWN,
XIANTAO CITY, HUBEI PROVINCE, CHINA**

has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA SUNGO TECHNICAL SERVICE INC.
Communications: 6050 W EASTWOOD AVE APT 201, CHICAGO,
ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.com

**Registration Number:3014222396
Device Listing#: See annex**

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.



**Executive Director
Issued: Dec. 23 2019
Cert. No.: 2006US514538
Expiration Date: Dec. 31 2020**



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

Annex to Cert. No.: 2006US514538

Listing No	Code	Device Name
D309738	KHA	MASK, SCAVENGING (Mask)
D309739	FYF	CAP, SURGICAL (Cap)
D309740	FXP	COVER, SHOE, OPERATING-ROOM (Shoe Cover)
D309741	OEA	NON-SURGICAL ISOLATION GOWN (Coverall, Isolation Gown, Lab Coat)
D309742	FYE	DRESS, SURGICAL (Surgical Gown)
D309743	KME	BEDDING, DISPOSABLE, MEDICAL (Bed Sheet)

END OF THE ANNEX





Compliance Report

Applicant: XIANTAO LIJUN NON-WOVEN PRODUCTS CO., LTD
Address: NO.138 QIANQIU SOUTH STREET, PENGCHANG TOWN,
XIANTAO CITY, HUBEI PROVINCE, CHINA
Product: Face Mask, Cap, Shoe Cover, Coverall, Isolation Gown,
Surgical Gown, Lab Coat, Bed Sheet
Type: See annex for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **02819**

Initial Issue Date: **24 Nov 2017**



Tony Chen

General Manager (Signature)



Annex to Report (No. 02819)

XIANTAO LIJUN NON-WOVEN PRODUCTS CO., LTD

Product Name	Type
Face Mask	(18+20+25g), (20+20+25g), (12cm*9cm, 14.5cm*9cm, 17.5cm*9cm) , (With valve /Without valve) or as the clients' request
Cap	(18" 19"20" 21"24"), (9g -- 30g), (Single elastic Double elastic) or as the clients' request
Lab Coat	S, M, L, XL, XXL, XXXL, XXXXL or as the clients' request
Isolation Gown	S, M, L, XL, XXL, XXXL, XXXXL or as the clients' request
Surgical Gown	S, M, L, XL, XXL, XXXL, XXXXL or as the clients' request
Coverall	S, M, L, XL, XXL, XXXL, XXXXL or as the clients' request
Shoe Cover	15cm*36cm, 16cm*38cm, 15cm*40cm, 1.5g--55g or as the clients' request
Bed Sheet	120cm*180cm, 120cm*220cm, 120cm*240cm or as the clients' request

This annex is only valid if attached to the report mentioned above.