Certificado Nº 981114

MASCARILLA QUIRURGICA ALTO RIESGO DE 3 CAPAS

3 PLY HIGH RISK SURGICAL MASK

TIPO: C/ GOMAS */ TYPE : W/ ELASTIC*

CODIGO/ *CODE*	**EAN-13**	**PRESENTACION** / *PRESENTATION*
040062	8 435125 400817	C/DISPENSADORA 50 UDS ./40 x 50 Uds. CARTÓN (2.000 Uds.) *C / DISPENSER 50 UNITS / 40 x 50 Units CARTON (2.000 Units)*

CARACTERISTICAS. */ CHARACTERISTICS.*

- Mascarilla con filtro de forma plana/rectangular, con pliegues. *Mask with filter of flat / rectangular shape, with folds.*
- Fabricadas en T.N.T. */ Made in T.N.T.*
- Exentas de latex / *Latex free*
- 3 capas (1 papel / 1 filtro / 1 TNT). / *3 layers (1 paper / 1 filter / 1 TNT).*
- Con alto poder de filtración >98%. / *With high filtering power> 98%.*
- Color azul. / *Color blue.*
- Espesor filtro = 10 micrones. / *Filter thickness = 10 microns.*
- Resistencia de respiración = 23 pa / *Breathing resistance = 23 pa*
- Tamaño 9 x 17,5 cm. / *Size 9 x 17.5 cm*
- Adaptable mediante gomas */ Adaptable by rubbers*
- Fabricadas para minimizar riesgo de contaminación. / *Manufactured to minimize the risk of contamination.*
- Tiras de aluminio para su adaptación a la nariz. / *Aluminum strips for adaptation to the nose.*
- Tipo IIR */ Type IIR*
- Marca: " K" / *Mark: "K".*
-
- Marcado " CE" : Clase I, DECLARACION DE CONFORMIDAD.
- *"CE" marking: Class I, DECLARATION OF CONFORMITY.*

XIAN TAO YUNTIAN NON-WOVEN PRODUCTS CO., LTD.
21 PENGCHENG ROAD, PENGCHENG , XIAN TAO, HUBEI, CHINA

DECLARATION OF CONFORMITY

MASK 3 PLY

We, like manufacturer of Non - Sterile MASK 3 PLY and according to European Council Directive 93/42/EEC dated on 14 June 1993, where above indicated articles are classified as Class I medical devices, declare:

That we are manufacturing for our EU Representative:

And we do hereby declare that the above mentioned product, described under the Technical Documentation, does conform to the requirements set out in Annex VII of Council Directive 93/42/EEC, so that our product is allowed to bear the "CE" mark

Date: May 12Th , 2020

Signed: LIU XINQI
Sales Manager

XIAN TAO YUNTIAN NON WOVEN PRODUCTS CO.,LTD.

XIAN TAO YUNTIAN NON-WOVEN PRODUCTS CO., LTD.
21 PENGCHENG ROAD, PENGCHENG , XIAN TAO, HUBEI, CHINA

DECLARATION for:

MASK 3 PLY

We, like manufacturer of Non – Sterile MASK 3 PLY and according to European Council Directive 93/42/EEC dated on 14 June 1993, where above indicated articles are classified as Class I medical devices, declare:

That we are manufacturing for our EU Representative:

And we do hereby declare that the above mentioned product, described under the Technical Documentation, does conform to the requirements set out in UNE-EN 14683:2019+AC:2019 with the following main results from external test report:

BFE: 99.3%
PFE: 94,74%

Date: May 12Th , 2020

Signed: LIU XINQI
Sales Manager

XIAN TAO YUNTIAN NON WOVEN PRODUCTS CO.,LTD.

广检集团 GTTC

CMA 170000113982 ilac-MRA CNAS TESTING CNAS L10314

TEST REPORT (Electronic version)

扫码下载报告

VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: XATE-9854-04

No:200099628 ISSUE DATE:2020-05-08

APPLICANT: XIANTAO YUNTIAN NON WOVEN PRODUCTS, CO, LTD
ADDRESS: 21 PENGCHANG ROAD, PENGCHANG, XIANTAO, HUBEI, CHINA

INFORMATION CONFIRMED BY APPLICANT:

NON-WOVEN DISPOSABLE FACE MASK

QUANTITY: THIRTY-FIVE PIECES

DATE RECEIVED/DATE TEST STARTED: 2020-04-27

CONCLUSION:

BACTERIAL FILTRATION EFFICIENCY	M
BREAKING STRENGTH OF MASK STRING AND JUNCTION BETWEEN MASK STRING AND MASK BODY	M
PARTICLE FILTRATION EFFICIENCY	M
COLOUR FASTNESS TO RUBBING[OUTER]	M
BANNED AZO COLOURANTS	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"---" -NO COMMENT

REMARK:
THE DECISION INDICATORS ARE DERIVED FROM THE GROUP STANDARD REQUIRED BY CLIENT (T/GDBX 025-2020). OUR INSPECTION CAPACITY AUTHORIZED BY CMA COVERS THE INSPECTION ITEMS T/GDBX 025-2020 .
THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200099627.
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R.CHINA.

APPROVED BY: 马楠

Nan Ma ENGINEER

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161

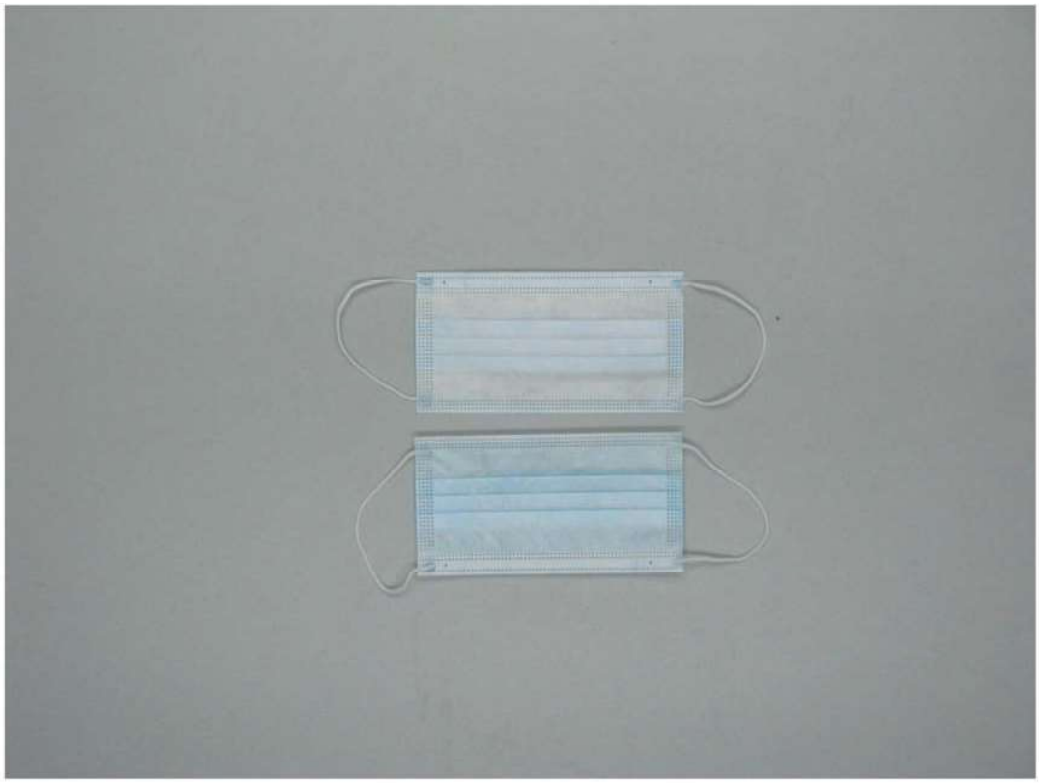
Certificado Nº 981114

广检集团 GTTC

170000113982

TEST REPORT (Electronic version)

No:200099628



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总部：广州市番禺区珠江路1号
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电话:020-61994598/61994599
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TEST REPORT

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No:200099628

BACTERIAL FILTRATION EFFICIENCY(%)

(YY 0469-2011 ANNEX B, TEST BACTERIA: STAPHYLOCOCCUS AUREUS ATCC 6538, TEST AREA: 40cm^2 , FLOW RATE: 28.3L/min, MEAN PARTICLE SIZE: 3.0μm, RESULT OF THE POSITIVE CONTROL: 1.9×10^3 CFU, RESULT OF THE NEGATIVE CONTROL: ＜1CFU)

		REQUIREMENT
BFE_1	99.2	≥95(GRADE A)
BFE_2	99.3	(T/GDBX 025-2020)
BFE_3	99.4	

BREAKING STRENGTH OF MASK STRING AND JUNCTION BETWEEN MASK STRING AND MASK BODY

(YY 0469-2011 5.4)

	REQUIREMENT
PASS	≥10N
	(T/GDBX 025-2020)

PARTICLE FILTRATION EFFICIENCY(%)

(YY 0469-2011 5.6.2, AIR FLOW: 30L/min, AEROSOL: NaCl, AEROSOL CONCENTRATION: 15mg/m^3 , TEMP: 23.3℃, RH: 36.2%)

	REQUIREMENT
MINIMUM 94.74	≥50
	(GRADE A)
	(T/GDBX 025-2020)

COLOUR FASTNESS TO RUBBING(GRADE)[OUTER]

(GB/T 29865-2013)
(GB/T 29865-2013 MOD ISO 105-X16:2001)

		REQUIREMENT
DRY	4-5	≥3-4
WET	4-5	≥3
		(T/GDBX 025-2020)

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广检集团 GTTC

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TEST REPORT

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BANNED AZO COLOURANTS

TEST METHOD: GB/T 17592-2011, GENERAL PRETREATMENT

FORBIDDEN AMINE	CAS NO.	REQUIREMENT (mg/kg)	RESULT (mg/kg)
4-aminobiphenyl	[92-67-1]	≤20	N
benzidine	[92-87-5]	≤20	N
4-chloro-o-toluidine	[95-69-2]	≤20	N
2-naphthylamine	[91-59-8]	≤20	N
o-aminoazotoluene	[97-56-3]	≤20	N
5-nitro-o-toluidine	[99-55-8]	≤20	N
p-chloroaniline	[106-47-8]	≤20	N
2,4-diaminoanisole	[615-05-4]	≤20	N
4,4' -diaminobiphenymethane	[101-77-9]	≤20	N
3,3' -dichlorobenzidine	[91-94-1]	≤20	N
3,3' -dimethoxybenzidine	[119-90-4]	≤20	N
3,3' -dimethylbenzidine	[119-93-7]	≤20	N
3,3' -dimethyl-4,4' -diaminobiphenylmthane	[838-88-0]	≤20	N
p-cresidine	[120-71-8]	≤20	N
4,4' -methylene-bis-(2-chloroaniline)	[101-14-4]	≤20	N
4,4' -oxydianiline	[101-80-4]	≤20	N
4,4' -thiodianiline	[139-65-1]	≤20	N
o-toluidine	[95-53-4]	≤20	N
2,4-toluylendiamine	[95-80-7]	≤20	N
2,4,5-trimethylaniline	[137-17-7]	≤20	N
o-anisidine	[90-04-0]	≤20	N
2,4-xylidine	[95-68-1]	≤20	N
2,6-xylidine	[87-62-7]	≤20	N
4-aminoazobenzene	[60-09-3]	≤20	N

"N" MEANS LESS THAN THE DETECTION LIMIT OF 5mg/kg

RATING ACCORDING TO T/GDBX 025-2020.

OVERALL RATING PASS

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

———End of Report———

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