

MASCARILLA QUIRURGICA ALTO RIESGO DE 3 CAPAS

TIPO : C/ GOMAS



CODIGO	EAN-13	PRESENTACION
040062	 8 435125 400817	C/DISPENSADORA 50 UDS ./40 x 50 Uds. CARTÓN (2.000 Uds.)

CARACTERISTICAS.

- Mascarilla con filtro de forma plana/rectangular, con pliegues.
- Fabricadas en T.N.T.
- Exentas de latex
- 3 capas (1 papel / 1 filtro / 1 TNT).
- Con alto poder de filtración >98%.
- Color azul.
- Espesor filtro = 10 micrones.
- Resistencia de respiración = 23 pa
- Tamaño 9 x 17,5 cm.
- Adaptable mediante gomas
- Fabricadas para minimizar riesgo de contaminación.
- Tiras de aluminio para su adaptación a la nariz.
- Tipo IIR
- Marca: " K" .
- Marcado " CE" : Clase I, DECLARACION DE CONFORMIDAD.

DECLARACION DE CONFORMIDAD CE

MASCARILLA QUIRURGICA ALTO RIESGO 3 CAPAS CON ELASTICOS / CON CINTAS

Las mascarillas no estériles están incluidas en la categoría de clase I, según el Reglamento (UE) 2017/745 del Parlamento Europeo y del Consejo, de 5 de abril de 2017 relativa a productos sanitarios.

Nuestras mascarillas cumplen con los requisitos establecidos en la UNE-EN

14683:2019+AC:2019 de Requisitos y Métodos de Ensayo para las Mascarillas Quirúrgicas.

Fecha: Madrid, 18 de Marzo de 2.020.

Firmado: Clara Fernández Fernández

Posición: Técnico Garante

KRAPE, S.A.


KRAPE, S.A.
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Técnico Garante

XIAN TAO YUNTIAN NON-WOVEN PRODUCTS CO., LTD.
21 PENGCHENG ROAD, PENGCHENG , XIAN TAO, HUBEI, CHINA
TEL: (86-728) 265176 FAX: (86-728) 2614008

DECLARATION OF CONFORMITY
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:

KRAPE, S.A.
EDUARDO TORROJA, 31
28914-LEGANES-MADRID (SPAIN)

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

Date: October 28Th , 2019.

XIAN TAO YUNTIAN NON WOVEN
PRODUCTS CO.,LTD.


LIU XINQI
Sales Manager

MASK TEST REPORT I

Sample Source	XIANTAO YUNTIAN NON WOVEN PRODUCTS CO. LTD.
Sample Identification:	Refer to Table 1
Deviations.	None
Statement of Uncertainty:	If applicable, available upon request
Minimum Conditioning	4 hours at $21 \pm 5^{\circ}\text{C}$ and $85 \pm 5\%$ relative humidity
Andersen Sampler Flow Rate:	28.3 Umin (1 CFM)
Sample Received Date	06 Jul 2018
Lab Phase Start Date:	23 Jul 2018
Lab Phase Completion Date.	05 Aug 2018
Report Issue Date:	05 Aug 2018

PROCEDURE

The Bacterial Filtration Efficiency (BFE) procedure is performed to determine the filtration efficiency of various material and filtration devices using a challenge organism of *Staphylococcus aureus*. This procedure complies with ASTM F2101 The Differential Pressure (Delta P or 6P) test, performed to determine the air exchange differential (breathability) of porous materials

TABLE 1. Synthetic Blood Penetration Resistance

Sample Identification: Face Mask

Test Pressure: 120 mm HG

SAMPLE NUMBER	SYNTETIC BLOOD PENETRATION	SAMPLE NUMBER	SYNTETIC BLOOD PENETRATION
1	None Seen	17	None Seen
2	Yes	18	None Seen
3	None Seen	19	None Seen
4	None Seen	20	None Seen
5	None Seen	21	None Seen
6	None Seen	22	None Seen
7	None Seen	23	None Seen
8	None Seen	24	None Seen
9	None Seen	25	None Seen
10	None Seen	26	None Seen
11	None Seen	27	Yes
12	None Seen	28	None Seen
13	None Seen	29	None Seen
14	None Seen	30	None Seen
15	None Seen	31	None Seen
16	None Seen	32	None Seen

Date: Madrid August 09th, 2.019.

Signed: A. Fernandez

Position: Director

KRAPE, S.A.



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MASK TEST REPORT II

Sample Source	XIANTAO YUNTIAN NON WOVEN PRODUCTS CO. LTD.
Sample Identification:	Refer to Table 1
Deviations.	None
Statement of Uncertainty:	If applicable, available upon request
Reference Masks:	8 out of 8 passed
Lab. Conditions:	19°C and 42% relative humidity (Rh)
Sample Received Date	06 Jul 2018
Lab Phase Start Date:	23 Jul 2018
Lab Phase Completion Date.	05 Aug 2018
Report Issue Date:	05 Aug 2018

Procedure : This report describes details for testing surgical face masks and other types of protective clothing materials designed to shield against fluid penetration. The purposes of this procedure are to simulate an arterial spray and then evaluate the effectiveness of the material in protecting the healthcare worker from possible exposure to blood and other body fluids. This test method was designed to comply with ASTM F-1862.

Samples were conditioned for a minimum of 4 hours at a temperature of $21 \pm 5^\circ \text{C}$ and a relative humidity of $85 \pm 5\%$. A specimen was mounted on a fixture, 12 inches from the tip of the cannula, and subjected to a 2 ml volume spray of the synthetic blood. Each sample was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area. After every sixteen specimens, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 ml of synthetic blood

Results. To meet an Acceptable Quantity Level of 4 0%, it is required that 29 of the 32 specimens pass the test. The results are summarized in Table 1

TABLE 1 Results from Sample identification Face Mask

TEST	RESULT
BFE at 3.0 microm	99,9 %
BFE at 0.1 microm	98,5 %
Delta P. Air permeability	4.8
Flammability	Class I
Fluid Resistance (mmHG)	124
Control average (CFU)	1892
Mean Particle Size	2.90 um.

- There were no detected colonies on any of the Andersen sampler plates for this sample.
- Considering results obtained from samples analysed, type of masks is IIR, where BFE is over 98% for The mean particle size and Fluid Resistance is ≥ 120 mmHG

Date: Madrid August 09th, 2.019.

Signed: A. Fernandez

Position: Director

KRAPE, S.A.





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