CE EN 14683

IMADEX
IMPORTAÇÃO E COMERCIO DA MADEIRA, LDA

MÁSCARA CIRURGICA DE ALTA FILTRAÇÃO, TIPO II

Descrição do Produto

As máscaras cirúrgicas consistem em três camadas de material não tecido:

Camada Externa
100% Polipropileno Azul

Camada Central
Tecido Não Tecido Fundido Branco

Camada Interna
100% Polipropileno Branco

Adequado para uso Hospitalar e uso em geral. Excelente pelo seu conforto e respirabilidade.

Especificações

Especificações do Tamanho e Aparência do Produto

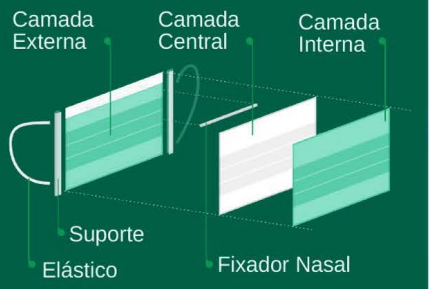
1 Comprimento da máscara: >170 mm

2 Expanção em largura: 165 mm.
Largura de 95 mm, com camadas centrais superiores a 10 mm.
Fixador nasal localizado na parte superior da máscara.
Parte externa da máscara com cor mais escura.

3 Largura do suporte inferior a 10 mm. Posição do fixador nasal inferior a 16 mm.

4 Fixador nasal: Comprimento> 80mm; Largura aproximadamente 3 mm.

5 Elástico: 180 mm de comprimento e 3 mm de diâmetro, composto por poliéster, elastano e outros materiais soldados na camada interna a menos de 10 mm da borda

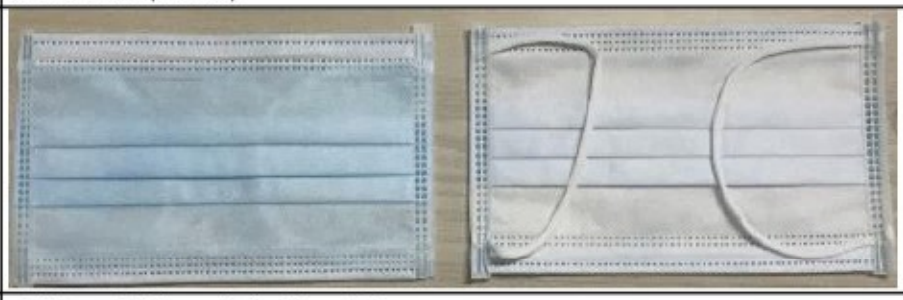


Parâmetros da Máscara Cirúrgica

Nome	Produto
Produto	Máscara Cirúrgica de Alta Filtração, Tipo II
Material	Camada Externa (Barreira Liquida) - Tecido Não Tecido de Polipropileno Camada Central (Filtro Bacteriano) – Tecido Não Tecido Fundido Branco, 25g/m2 +/-10% Camada Interna (Contacto Facial) – Tecido Não Tecido de Polipropileno Branco, 27g/m2 +/-10% Fixador Nasal: Polipropileno (PP) Elástico: 75D de alta elasticidade, sem latex
Modelo	Plano
Tamanho	175*95 mm
Aplicação e Finalidade	Uso Hospitalar, para proteção em ambiente cirúrgico e outros. BFE > 99%
Data de Validade	2 anos após data de produção
Esp. da Embalagem	Caixa com 50 Máscaras. Dimensão: 18 x 10 x 8 cm (L x W x H)
Esp. Caixa Transporte	20 Embalagens. Dimensão: 52 x 38 x 18 cm (L x W x H)
Armazenamento	Armazenar em local bem ventilado, com humidade relativa abaixo dos 85% Evitar uso em altas temperaturas e a exposição a chamas

Technical Data Sheet

Date: Mar. 19, 2020 Version: A/0

Art.No.:	**80-901**
Description:	**Face mask, 3ply, with elastic, blue color**
Material:	-First/outer layer (liquid barrier): Polypropylene Spunbond Nonwoven, blue, 27g/m2±10%, -Second/middle layer (bacteria filter): Meltblown Nonwoven, white, 25g/m2±10%, -Third/inner layer (face contact): Polypropylene Spunbond Nonwoven, white, 27g/m2±10%, -Nose wire: PP, length:110mm±5mm, width: 3mm±0.2mm, height:0.5mm -Ear loop: 75D, high elasticity, latex free
Size:	175x95mm (±2mm)
Product picture:	
Quality requirement:	-BFE: ＞99 %, particle Size: 3.0 μm -Differential pressure: ＜40 ΔP (Pa/cm²) -Appearance: no foreign material, dirt, broken, additional material processed ＜3mm. -Tensile strength of ear loop fixed to the mask: ＞10N.
Primary packing:	**Folding box**
Dimension:	18x10x8cm (LxWxH)
Material:	Paperboard, 400g/m2, stuck together by glue, not by staple.
Printing:	According to the requirement of customer.
Content/box:	50 pcs/box
Secondary packing:	**Brown carton**
Dimension:	52x38x18cm (LxWxH)
Material:	Cardboard, brown, thickness 5mm, stuck together by glue, not by staple.
Printing:	Blank printing
Content/carton:	20 boxes/carton

Date	Version	Revision history	Prepared by
Mar. 19, 2020	A/0	/	Sindy

bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 655951**

Issued To:

In respect of:

Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive: dressing sets, haemodialysis sets, suture sets, suture removal sets, urinary catheter sets, pressure ulcer sets, anaesthesia sets, surgical sets, disinfection sets.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2017-08-01** Date: **2019-02-27** Expiry Date: **2022-11-29**

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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

Test Report No.: 721635655-1
Report Date: 8 November 2017

ORIGINAL

SUBJECT **Microbiological Test**

TEST LOCATION **TÜV SÜD China**

TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai 201108, P.R. China

CLIENT NAME

CLIENT ADDRESS

TEST PERIOD 11-Oct-2017~23-Oct-2017

Prepared By

(Chen Rui)
Report Drafter

Authorized By

(Shen Li)
Authorized Signatory

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ORIGINAL

Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask material.

2. Sample description was given by the client

5183110020 (Baehr 01)
17.7x9.4cm-3ply

3. References

EN 14683:2014 Annex B

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538
4.2 Peptone water
4.3 Tryptic Soy Broth(TSB)
4.4 Tryptic Soy Agar(TSA)
4.5 Bacterial filtration efficiency test apparatus
4.6 Six-stage viable particle Anderson sampler
4.7 Flow meters

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately $5x10^5$ CFU/mL.
6.2 Adjust the flow rate throuth the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated form the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen in contact with the challenge.
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control afer completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (35±2)°C for (48±4) h.

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6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacturer of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE(\%)=\frac{C-T}{C} \times 100$$

Where:

C= average plate count total for positive controls

T= plate count total for sample

8. Test results

Test Items*		Test Results	Test Methods
Bacterial Filtration Efficiency(BFE)(%) *Staphylococcus aureus* ATCC 6538	1	99.2	EN 14683:2014 Annex B
	2	99.4	
	3	99.5	
	4	99.1	
	5	99.1	

Note: 1: Control average: 2050 CFU.

2: Mean particle size:3.0 μm.

3: Testing side: inside of specimen.

4: Testing area: 39.5cm^2.

5:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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Test Report No.: 721635655-2
Report Date: 8 November 2017

ORIGINAL

SUBJECT	**Physical Test**
TEST LOCATION	**TÜV SÜD China**
	TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	
CLIENT ADDRESS	
TEST PERIOD	11-Oct-2017~30-Oct-2017

Prepared By

(Chen Rui)
Report Drafter

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ORIGINAL

Differential pressure of a medical face mask

1. Purpose

The purpose of the test was to measure the differential pressure of a medical face mask.

2. Sample description was given by the client

5183110020 (Baehr 01)
17.7x9.4cm-3ply

3. Reference

EN 14683:2014

4. Apparatus

Differential pressure testing instrument

5. Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.
5.2 Each test specimen shall be conditioned at (21±5)℃ and (85±5)% relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.

6. Procedure

6.1 The test specimen is placed across the 2.5 cm diameter orifice(total area 4.9 cm^2) and clamped into place so as to minimize air leaks and that the tested area of the specimen will be in line and across the flow of air.
6.2 The pump is started and the that tested area of the specimen will be in line and across the flow of air.
6.3 The manometers M1 and M2 are read and recorded.
6.4 The procedure described in steps 6.1~6.3 is carried out on 5 different areas of the mask and readings averaged.

7. Calculation

For each test specimen calculate the different pressure ΔP as follows:

$$\Delta P=\frac{(Xm1-Xm2)}{4.9}$$

X_{m1}: is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;

X_{m2}: is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;

4.9 is the cm^2 area of the test material;

ΔP is the different pressure per cm^2 of the test material expressed in Pa.

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8. Test results

Test Items*		Test Results	Test Methods
Differential Pressure Test (Pa/cm^2)	1	34.1	EN 14683:2014
	2	35.6	
	3	36.4	
	4	35.4	
	5	38.9	

Note:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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Doc. No.	KSX/TD-MMM-017	Title	EC Declaration of Conformity of Nonwoven Face Mask		
Ver./Rev.No.	A/0	Issued Date	2020.02.28	Page/Total	1 / 1

EC Declaration of Conformity

Manufacturer Name:

Manufacturer Address:

Location of Manufacturer:

Authorized Representative:

Address of their Registered Place of Business:

Location be established:

Name of the device: Nonwoven Face Mask

Size of the device: 17.5cm x 9.5cm

UMDNS Code: 12477, Mask

Standard applied: EN 14683: 2019 + AC: 2019 E, Type II

Risk Class of the Device: Class I, based on Annex IX of MDD 93/42/EC

The conformity assessment procedure performed: Annex VII of MDD 93/42/EC

Declaration: This declaration of conformity is issued under the sole responsibility of . We hereby declare that the medical device specified above meet the provision of the EC Council Directives (MDD 93/42/EEC). This declaration is supported by the quality system approval to ISO 13485 by TÜV SÜD Product Service GmbH

All supporting documentation is retained at the premises of the manufacturer.

Date of Issue: 2020-03-14