


**Name**

MEDICAL / SURGICAL PROTECTIVE MASK

**Article number**

630400

**Product data**

<b>Type of Product</b>	Type IIR
<b>Colour</b>	White
<b>Sterility</b>	Non-sterile
<b>Layer</b>	3
<b>Description</b>	175 x 95 mm, Elastic Earloop, adjustable nosebridge, three layers

**Packing**

<b>Unit</b>	50 pcs/box
<b>Amount/Carton</b>	48 fp/kart
<b>Amount/Pallet</b>	24 kart/pallet

**Applicable Standards**

EN 14683:2019+AC:2019

 EU Directive 93/42/EEC on Medical Devices (MDD),  
Annex IX: Class I devices.

**Storage Suggestion**

Should be stored in a clean, dry, ventilated environment, related humidity below 80%

**Expire Date**

5 years after production date.

**Cautions**

Protects against the spread of particles and droplets. If package or product is damaged, prohibit to use!

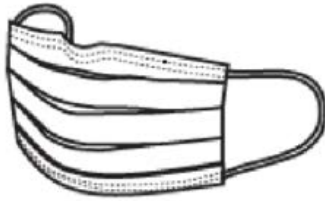
**If reused performance of the product may deteriorate, cross-contamination may occur!**
**Performance: (EN 14683:2019+AC:2019)**

- Bacterial Filtration Efficiency (BFE): 98,85 %
- Differential pressure: 23 Pa/cm<sup>2</sup>
- Microbial Cleanliness: 22 cfu/g
- Splash resistance pressure: 16 kPa

**Product Description**

- Soft and pleasant to skin
- High comfort and easy to breath in
- Type IIR classification





1. Unfold the mask, hang the earloops on the ears. The nosebridge shall face upwards



2. Pull the mask folds down to the lower jaw so it fully covers the nose, mouth and chin. Fix the nose bridge bar.



3. Fix the nose bridge bar accordingly, to prevent air leakage.

### How to put on a face mask

1. Clean your hands with soap and water or hand sanitizer before touching the mask.
2. Remove a mask from the box and make sure there are no obvious tears or holes in either side of the mask.
3. Determine which side of the mask is the top. The side of the mask that has a stiff bendable edge is the top and is meant to mold to the shape of your nose.
4. Determine which side of the mask is the front. The colored side of the mask is usually the front and should face away from you, while the white side touches your face.
5. Face Mask with Ear loops: Hold the mask by the ear loops. Place a loop around each ear.
6. Pull the bottom of the mask over your mouth and chin.
7. Mold or pinch the stiff edge to the shape of your nose.

### How to remove a face mask

1. Clean your hands with soap and water or hand sanitizer before touching the mask. Avoid touching the front of the mask. The front of the mask is contaminated. Only touch the ear loops/ties/band. Follow the instructions below for the type of mask you are using.
2. Face Mask with Ear loops: Hold both ear loops and gently lift and remove the mask
3. Throw the mask in the trash. Clean your hands with soap and water or hand sanitizer

### Warnings

- Do not touch the outside of the facemask. If you do, wash your hands properly.
- This mask is only single use. Do not reuse.
- The mask should be replaced in time. Long-term use is not recommendable.
- It is suggested to stop using it if there is any unfitness or adverse reactions in the process of wearing
- The product is not washable, please ensure that it is used within the valid period.
- Store in a dry, ventilated place and stay away from fire and flammable materials
- Change mask if wet, heavy breathable, dirty or at least within (4) hours

Report No: 2020030606

Sample Accepted on: 25.05.2020  
Report Date: 03.06.2020  
Total number of pages: 9 (Pg)Sample ID: **FACE MASK**Medical surgical protective masks (3ply) white  
Üç katlı medikal cerrahi koruma maskesi (beyaz)

TEST	METHOD	Specimen	RESULT
* Medical face masks - Requirements and test methods	EN 14683+AC 2019	Medical and surgical mask (3ply)	PASS
			TYPE IIR



Seal

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**Environment**

The requirements and standards apply to equipment intended for use in

X	Residential (domestic) environment
X	Commercial and light-industrial environment
X	Industrial environment
X	Medical environment



## Requirements and test methods

This European Standard specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

### General

All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile state.

## Method for in-vitro determination of bacterial filtration efficiency (BFE)

### Principle

A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

## Reagents and materials

### General

Describe commercially available solutions of tryptic soy agar and tryptic soy broth. Other variants may be suitable.

### Tryptic soy agar

Formula/liter:

Enzymatic digest of casein	15 g
Enzymatic digest of soybean meal	5 g
Sodium chloride	5 g
Agar	15 g
Final pH	7,3 ± 0,2 at 25 °C

**Tryptic soy broth**

Formula/liter:

Enzymatic digest of casein	17 g
Enzymatic digest of soybean meal	3 g
Sodium chloride	5 g
Dextrose	2,5 g
Final pH	7,3 ± 0,2 at 25 °C

**Peptone Water**

Formula/liter:

Peptone	1 g
Sodium chloride	5 g
Final pH	7,3 ± 0,2 at 25 °C

**Preparation of bacterial challenge**

Staphylococcus aureus shall be inoculated into 30 ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at a temperature of (37 ± 2) °C for (24 ± 2) h. The culture shall then be diluted in peptone water to give a concentration of approximately 5 × 10<sup>5</sup> cfu/ml.

The bacterial challenge shall be maintained at (2 200 ± 500) cfu per test. The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see B.6.3) and the dilution of the challenge suspension adjusted accordingly. The mean particle size in the bacterial challenge shall be maintained at (3,0 ± 0,3) µm (see B.6.9).

**Procedure**

Assemble the apparatus in accordance with the flow chart shown in Figure B.1.

Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.

Perform a positive control run without a test specimen. Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28,3 l/min. Deliver the bacterial challenge for 1 min. Maintain the airflow through the impactor for 2 min. Then remove the plates from the impactor. Ensure that each plate is numbered to indicate its position in the impactor.

Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.

Repeat this procedure for each test specimen.

After the last test specimen has been tested, perform a further positive control run.

Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.

Incubate all the plates at (37 ± 2) °C for (48 ± 4) h.

For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of cfu collected by the impactor using the "positive hole" conversion table1) in accordance with the instructions of the cascade impactor manufacturer. For the two positive control runs, take the mean of the two totals. From the positive control plates calculate the mean particle size of the bacterial challenge aerosol using the "positive hole" conversion table in accordance with the instructions of the cascade impactor manufacturer.

#### Calculation of bacterial filtration efficiency

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$$B = (C - T) / C \times 100$$

Where;

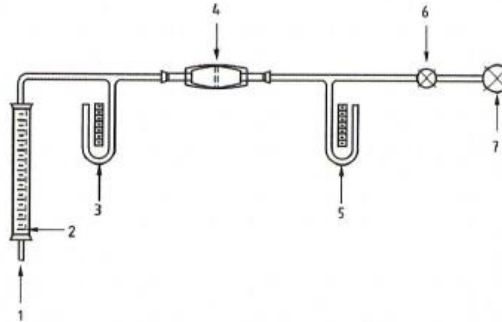
C is the mean of the total plate counts for the two positive control runs;

T is the total plate count for the test specimen.

#### **Method for determination of breathability (differential pressure)**

##### **Principle**

A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure 1. Water-filled manometers (M1 and M2) are used to measure the differential pressure. A flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the airflow rate.



##### **Key**

- 1 air inlet
- 2 flow meter
- 3 manometer M1
- 4 filter material

- 5 manometer M2
- 6 valve
- 7 vacuum pump

**Figure 1 — Apparatus for measuring air resistance**



### Procedure

The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm<sup>2</sup>) and clamped into place so as to minimise air leaks and that the tested area of the specimen will be in line and across the flow of air.

The pump is started and the flow of air adjusted to 8 l/min.

The manometers M1 and M2 are read and recorded.

The procedure described in steps 1 through 3 is carried out on 5 (or appropriate number of) different areas of the mask and the readings averaged.

### Calculation of differential pressure

For each test specimen calculate the differential pressure  $\Delta P$  as follows:

$$\Delta P = (X_{m1} - X_{m2})/4,9$$

Where;

X<sub>m1</sub> is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;

X<sub>m2</sub> is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;

4,9 is the cm<sup>2</sup> area of the test material;

$\Delta P$  is the differential pressure per cm<sup>2</sup> of test material expressed in Pa.

### Splash resistance

When tested in accordance with ISO 22609 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.

### Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be  $\leq 30$  cfu/g tested (see Table 1).

To determine the mask's bioburden according to EN ISO 11737-1, follow the procedure below:

The number of masks that shall be tested is minimum 5 (five), but can be greater if necessary to allow for an AQL of 4 %.

Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl & 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]).

The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45  $\mu$  filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 – 25) °C for TSA and SDA plates respectively.

The total bioburden is expressed by addition of the TSA and SDA counts.

In the report, indicate the total bioburden per mask and based on the mask weigh, the total bioburden per gram tested.



#### TEST REQUIREMENTS

Test	Type I <sup>a</sup>	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm <sup>2</sup> )	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

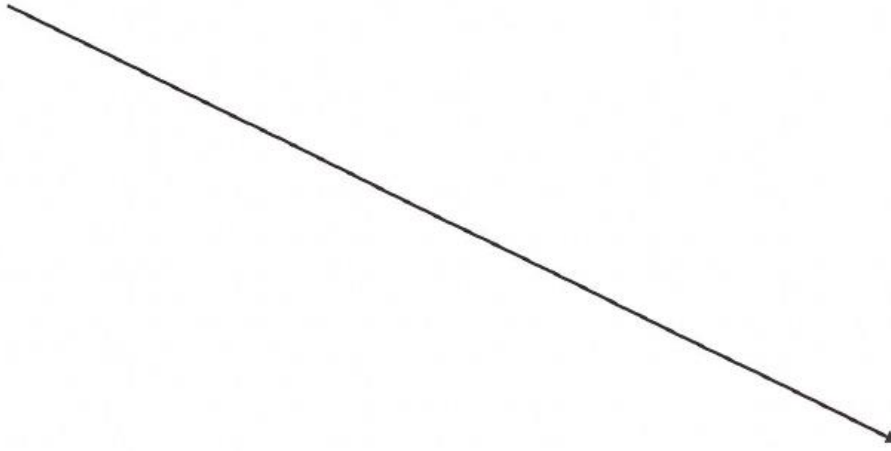
<sup>a</sup> Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

**TEST RESULTS**

EN 14683 Inspection

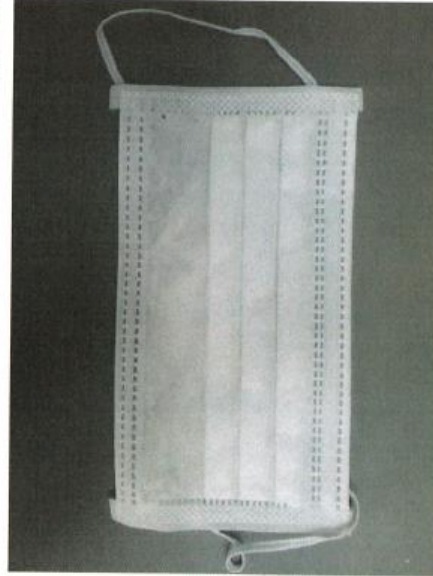
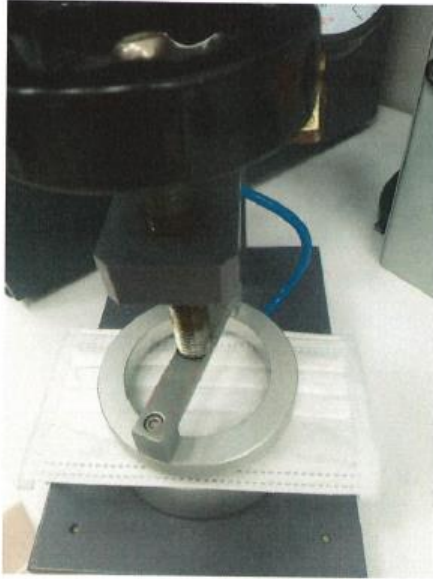
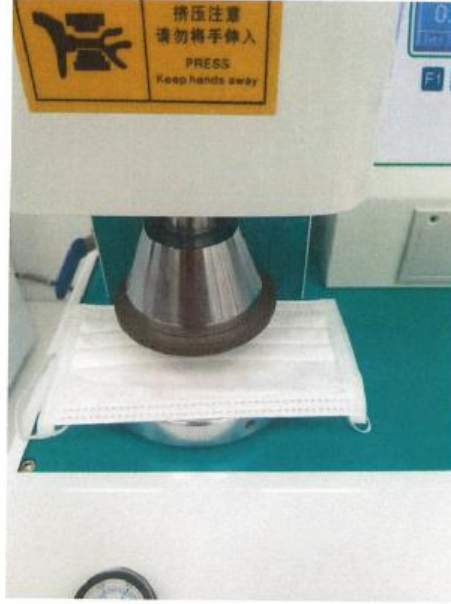
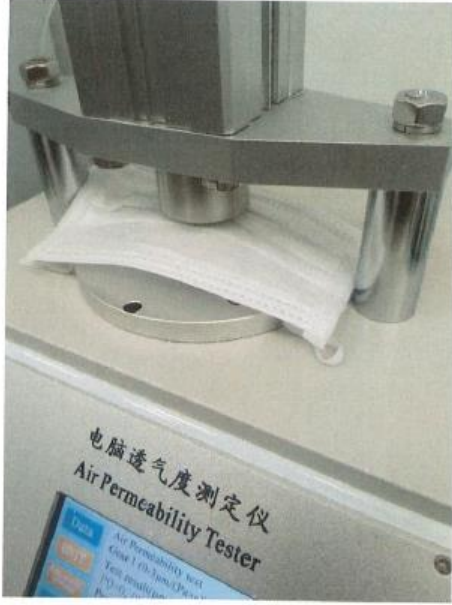
SAMPLE : FACE MASK (White)

Test	Type IIR	Result	Evaluation
Bacterial filtration efficiency (BFE), (%)	$\geq 98$	98,85	PASS
Differential pressure (Pa/cm <sup>2</sup> )	$< 60$	23	PASS
Splash resistance pressure (kPa)	$\geq 16$	16	PASS
Microbial cleanliness (cfu/g)	$\leq 30$	22	PASS



Free Area

**MASK IMAGES UNDER TEST**



**\*\*\*End of Report\*\*\***