Surgical masks —
Requirements and
test methods

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British Standard
National foreword

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Surgical masks - Requirements and test methods

Masques chirurgicaux - Exigences et méthodes d'essai

Chirurgische Masken - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 19 September 2005.

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Foreword

This European Standard (EN 14683:2005) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2006, and conflicting national standards shall be withdrawn at the latest by May 2006.

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Introduction

The transmission of infective agents during surgical procedures in operating theatres and other medical settings can occur in several ways. Sources are e.g. noses and mouths of the surgical team. The main intended use of surgical masks is to protect the patients from infective agents from the noses and mouths of the staff and, in certain situations, additionally to protect the wearer against splashes of potentially contaminated liquids.
1 Scope

This European Standard specifies construction and performance requirements, and test methods for surgical masks intended to limit the transmission of infective agents from staff to patients and (in certain situations vice-versa) during surgical procedures in operating theatres and other medical settings with similar requirements.

This European Standard is not applicable to masks intended exclusively for the personal protection of staff.

NOTE 1 Standards for masks for use as respiratory personal protective equipment are available.

NOTE 2 Annex A provides information for the users of surgical masks.

2 Normative references

The following referenced documents are indispensable for the application of this European Standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM F1862, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1 surgical mask
medical device covering the mouth, nose and chin providing a barrier to minimise the direct transmission of infective agents between staff and patient

NOTE Transmission of blood-borne agents from patients to staff may occur via splashes.

3.2 bacterial filtration efficiency (BFE)
effectiveness of a surgical mask in capturing aerosol droplets containing bacteria

3.3 differential pressure
pressure drop across a surgical mask under specific conditions of air flow, temperature and humidity

NOTE The differential pressure is an indicator of the "breathability" of the mask.

3.4 colony forming unit (cfu)
particle containing one or more bacterial cells which gives rise to a single bacterial colony on a culture plate

3.5 infective agent
micro-organism that has been shown to cause surgical wound infections or that might cause infection in the patient or in members of the surgical team
3.6 surgical procedure
surgical intervention penetrating skin or mucosa, performed by a surgical team under controlled environmental conditions

3.7 aerosol
suspension of solid, liquid, or solid and liquid, particles in a gaseous medium, the particles having a negligible falling velocity (see EN 132)

NOTE This velocity is generally considered to be less than 0.25 m/s.

4 Classification

Surgical masks specified in this European Standard are classified into two types according to bacterial filtration efficiency and differential pressure and each type is further divided according to whether or not the masks are splash resistant.

5 Requirements

5.1 General

5.1.1 Materials and construction

The surgical mask shall not disintegrate, split or tear during intended use.

5.1.2 Design

The surgical mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.

5.2 Performance requirements

5.2.1 Bacterial filtration efficiency (BFE)

When tested in accordance with Annex B, the bacterial filtration efficiency (BFE) of the surgical mask shall conform to the minimum value given for the relevant type in Table 1.

5.2.2 Breathability

When tested in accordance with Annex C, the differential pressure of the surgical mask shall conform to the value given for the relevant type in Table 1.

NOTE 1 If the use of a respiratory protective device as surgical mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant PPE standard(s).

NOTE 2 Differential Pressure is expressed in Pa. 1 Pa equals 9.806 times pressure expressed in mm water.

5.2.3 Splash resistance

When tested in accordance with ASTM F1862, the resistance of the surgical mask to penetration of splashes of liquid shall conform to the minimum value given for the relevant type in Table 1.
Table 1 — Performance requirements for surgical masks

<table>
<thead>
<tr>
<th>Test</th>
<th>Type I</th>
<th>Type IR</th>
<th>Type II</th>
<th>Type IIR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial filtration efficiency (BFE), (%)</td>
<td>≥ 95</td>
<td>≥ 95</td>
<td>≥ 98</td>
<td>≥ 98</td>
</tr>
<tr>
<td>Differential pressure (Pa)</td>
<td>&lt; 29,4</td>
<td>&lt; 49,0</td>
<td>&lt; 29,4</td>
<td>&lt; 49,0</td>
</tr>
<tr>
<td>Splash resistance pressure (mm Hg)</td>
<td>Not required</td>
<td>≥ 120</td>
<td>Not required</td>
<td>≥ 120</td>
</tr>
</tbody>
</table>

NOTE: Type IR and Type IIR are splash resistant types.

6 Testing requirements

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

Unless otherwise specified for a particular test, samples for testing shall be conditioned at (20 ± 2) °C and (65 ± 2) % relative humidity for the time required to bring them into equilibrium with atmosphere.

7 Labelling and information to be supplied

Annex 1 § 13 of the Medical Devices Directive (93/42/EEC) specifies the information that has to be specified on the packaging in which the surgical mask is supplied.

The following information shall be supplied in addition:

a) number of this European Standard;

b) type of mask (as indicated in Table 1).
Annex A
(informative)

Information for users

When breathing, speaking, coughing, sneezing etc. one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose. Those droplets quickly evaporate and leave nuclei suspended in the air. The majority of the nuclei are between 0,5 µm and 12 µm in diameter and especially the larger droplets can contain micro-organisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.

The surgical masks intended to be used in operating theatres and health care settings with similar requirements are designed to protect the working environment and not the wearer. When the primary intention is to protect the wearer from infection, the use of respiratory protective devices should be considered.

A special case, also covered by the European Medical Devices legislation, is that in which the wearer wishes to protect him/herself against splashes of potentially contaminated fluids. For this application this European Standard specifies performance requirements and gives a test method for a special class of surgical masks offering protection against splashes.

The degree of protection offered by a mask depends on a number of factors such as the filtration capacity and efficiency of the material and the fit of the mask on the wearer’s face. Different designs are suited for different applications and the careful choice of mask is therefore important in order to achieve the desired result.

The filtration capacity of mask materials can vary depending on the filter media. The fit of masks varies considerably from those which are held in place by ear loops fastened behind the wearer’s ears to those with tie bands around the head and a nose clamp that can be shaped to the wearer’s nose. The effect of a very good or less good fit can be tested in vivo whereas the filtration efficiency may be reproducibly tested in vitro.

The considerable variations in results when masks are tested in vivo results in the need for large groups of test subjects and observations. It is thus usual to characterize mask performance using in vitro tests of the material from which the mask is made. It is, however, important to consider the fit of the mask carefully when a mask for a certain application is chosen. Users should request such information from their suppliers.

A further factor to be considered is the capacity of the mask to absorb moisture from the exhaled air and thereby to maintain its performance over a longer period of time. The more advanced designs easily maintain their performance throughout even very long operations whereas the less advanced ones are intended only for short procedures.

The contamination risk resulting from hand contact with a used mask means that it is essential that the mask is taken off and disposed of when no longer worn over nose and mouth. When there is a further need for protection then a new mask should be put on. Touching a used face mask or putting on a new one should always be followed by a full hand disinfection procedure and a used mask should always be disposed of when no longer needed or between two procedures.

In summary, to use an appropriate mask is an effective means to protect the working environment from droplet contamination from nose and throat during health care procedures. Masks with very different performance are, however, available. Therefore such factors as infection risk and mask fit should be carefully considered when choosing a mask.
Annex B
(normative)

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

WARNING — *Staphylococcus aureus* is a pathogen. The relevant national provisions by law and hygienic instructions when dealing with pathogens shall be complied with.

B.1 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 surgical mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

B.2 Reagents and materials

B.2.1 Tryptic soy agar.

B.2.2 Tryptic soy broth.

B.2.3 Peptone water.

B.2.4 Culture of *Staphylococcus aureus* ATCC 209, growing on tryptic soy agar slants.

NOTE In case strain ATCC 209 is not available, strain ATCC 6538 may be used.

B.3 Apparatus

B.3.1 Six stage cascade impactor.

B.3.2 Nebulizer, capable of delivering particles with a mean size of 3.0 µm ± 0.3 µm.

B.3.3 Aerosol chamber, glass, 600 mm long and 80 mm in diameter.

B.3.4 Flow meters, capable of measuring a flow rate of 28.3 l/min

B.3.5 Pressure gauge, capable of measuring a pressure of 35 kPa to an accuracy of ± 1 kPa.

B.3.6 Erlenmeyer flasks, 250 ml and 500 ml capacity.

B.3.7 Peristaltic or syringe pump, capable of delivering 0.01 ml/min.

B.3.8 Vacuum pump, capable of maintaining a flow rate of 57 l/min.
B.4 Test specimens

Test specimens shall be cut from complete masks. Each specimen shall be minimum 100 mm by 100 mm and shall include all layers of the mask in the order in which they are placed in the complete mask. The number of specimens that shall be tested is minimum 5 (five), but can be greater and shall be increased if necessary to allow for an AQL of 4 %. All specimens tested shall be taken from areas representative from the mask to incorporate all / any variation in construction.

If required, condition the test specimens according to ISO 139. Otherwise, conditioning and testing can be carried out at normal room temperature. The method for conditioning shall be recorded in the test report.

B.5 Preparation of bacterial challenge

*Staphylococcus aureus* (B.2.4) 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 $5 \times 10^5$ cfu/ml.

The bacterial challenge shall be maintained at (2 200 ± 500) cfu per test. The bacterial challenge shall be determined for each day of testing on the basis of the 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).

B.6 Procedure

B.6.1 Assemble the apparatus in accordance with the flow chart shown in Figure B.1.

B.6.2 Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.

B.6.3 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.

B.6.4 Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.

B.6.5 Repeat this procedure for each test specimen.

B.6.6 After the last test specimen has been tested, perform a further positive control run.

B.6.7 Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.

B.6.8 Incubate all the plates at (37 ± 2) °C for (48 ± 4) h.

B.6.9 For each 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. 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 in accordance with the instructions of the cascade impactor manufacturer.
B.7 Calculation of bacterial filtration efficiency

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

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

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.

B.8 Test report

The following information shall be given in the test report;

a) number and date of this European Standard;
b) dimensions of the test specimens and the size of the area tested;
c) which side of the test specimen was facing towards the challenge aerosol;
d) flow rate during testing;
e) mean of the total plate counts of the two positive controls;
f) mean plate count of the negative controls;
g) bacterial filtration efficiency for each test specimen.

Figure B.1 — Principle of BFE Test Apparatus
Key
1 Drive mechanism
2 Bacterial suspension
3 Nebulizer
4 Filter
5 Aerosol chamber
6 High pressure air source
7 Test material
8 Microbial sampler
9 Outlet to sink
10 Condenser
11 Cold water inlet
12 Calibrated flow meter
13 Compressor (vacuum pump)

Figure B.2 — BFE test apparatus
Annex C
(normative)

Method for determination of breathability (differential pressure)

C.1 Principle

A device which measures the pressure differential 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 surgical mask material, as shown in Figure 2. Water-filled manometers (M1 and M2) are used to measure the pressure differential. 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.

![Diagram of apparatus for measuring air resistance](image)

Key

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<table>
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<tbody>
<tr>
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<td>Air inlet</td>
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<tr>
<td>2</td>
<td>Flow meter</td>
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<td>Manometer M1</td>
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<td>4</td>
<td>Filter material</td>
</tr>
<tr>
<td>5</td>
<td>Manometer M2</td>
</tr>
<tr>
<td>6</td>
<td>Valve</td>
</tr>
<tr>
<td>7</td>
<td>Vacuum pump</td>
</tr>
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</table>

Figure C.1 — Apparatus for measuring air resistance
C.2 Apparatus

C.2.1 Flow meter, capable of measuring an airflow of 8 l/min.

C.2.2 Manometers M1 and M2.

C.2.3 Electric vacuum pump.

C.2.4 Valve.

C.3 Test specimens

Test specimens 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. The number of specimens that shall be tested is 5 (five).

C.4 Procedure

C.4.1 The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm$^2$) and clamped into place so that the tested area of the specimen will be in line and across the flow of air.

C.4.2 The pump is started and the flow of air adjusted to 8 l/min.

C.4.3 The manometers M1 and M2 are read and recorded.

C.4.4 The procedure described in steps C.4.1 through C.4.3 is carried out on five different areas of the mask and the readings averaged.

C.5 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

- $X_{m1}$ is mm water pressure, manometer M1, mean of five test areas, low pressure side of the material;
- $X_{m2}$ is mm water pressure, manometer M2, mean of five test areas, high pressure side of the material;
- 4.9 is the cm$^2$ area of the test material;
- $\Delta P$ is the pressure differential per cm$^2$ of test material expressed as mm of water.

C.6 Test report

The following information shall be given in the test report:

a) number and date of this European Standard;

b) flow rate during testing;

c) differential pressure for each test specimen.
Annex ZA
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directive 93/42 concerning medical devices.

This European standard has been prepared under a mandate given to CEN by the European Commission to provide a means of conforming to the essential requirements of New Approach EU Directive 93/42/EEC Medical devices.

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Table ZA.1 — Correspondence between this European Standard and EU Directive 93/42/EEC Medical devices

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WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.
Bibliography


[3] EN 1041, *Information supplied by the manufacturer with medical devices*


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