

English Version

Medical face masks - Requirements and test methods

Masques à usage médical - Exigences et méthodes d'essai

Medizinische Gesichtsmasken - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 4 February 2014.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents	Page
Foreword.....	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 Classification.....	6
5 Requirements	7
5.1 General.....	7
5.2 Performance requirements	7
6 Labelling and information to be supplied	8
Annex A (informative) Information for users	9
Annex B (normative) Method for <i>in-vitro</i> determination of bacterial filtration efficiency (BFE).....	10
B.1 Principle.....	10
B.2 Reagents and materials	10
B.3 Apparatus	11
B.4 Test specimens	11
B.5 Preparation of bacterial challenge	11
B.6 Procedure	12
B.7 Calculation of bacterial filtration efficiency	12
B.8 Test report	12
Annex C (normative) Method for determination of breathability (differential pressure).....	15
C.1 Principle.....	15
C.2 Apparatus	16
C.3 Test specimens	16
C.4 Procedure	16
C.5 Calculation of differential pressure	16
C.6 Test report	16
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices	18
Bibliography	19

Foreword

This document (EN 14683:2014) 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of an identical text or by endorsement, at the latest by September 2014 and conflicting national standards shall be withdrawn at the latest by September 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 14683:2005.

In respect to EN 14683:2005, the following changes have been made:

- a) change/extension of title and scope to the more general and broader use for medical face masks;
- b) adjustment to ISO 22609 concerning the request for resistance to liquid splashes;
- c) addition of requirements for microbiological purity and general biocompatibility;
- d) adjustment of Table 1 on performance requirements for medical face masks;
- e) update of Annex A on user information;
- f) complete revision of Annex B on method for in-vitro determination of the bacterial filter performance in particular with regard to the testing conditions and the structure of the test apparatus;
- g) complete editorial revision, including update of all normative references, the Bibliography and Annex ZA on the relationships to the EU Directive 93/42/EEC.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

The transmission of infective agents during surgical procedures in operating theatres and other medical settings can occur in several ways. Sources are, for example, the noses and mouths of members of the surgical team. The main intended use of medical face masks is to protect the patient from infective agents and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids and viable particles. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations.

1 Scope

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.

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 medical face masks.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1)*

EN ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO 10993-5)*

EN ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization (ISO 10993-10)*

EN ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1)*

ISO 22609, *Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)*

3 Terms and definitions

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

3.1

medical face mask

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

Note 1 to entry: Transmission of blood-borne agents from patients to staff may occur via splashes.

3.2

bacterial filtration efficiency (BFE)

efficiency of the medical face mask material(s) as a barrier to bacterial penetration

Note 1 to entry: The BFE test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials.

3.3

differential pressure

air permeability of the mask, measured by determining the difference of pressure across the mask under specific conditions of air flow, temperature and humidity

Note 1 to entry: The differential pressure is an indicator of the "breathability" of the mask.

3.4
colony forming unit (cfu)
unit by which the culturable number of micro-organisms is expressed

Note 1 to entry: The culturable number is the number of micro-organisms, single cells or aggregates, able to form colonies on a solid nutrient medium.

3.5
cleanliness
freedom from unwanted foreign matter

Note 1 to entry: Such matter can be micro-organisms, organic residues or particulate matter.

3.5.1
cleanliness — microbial
freedom from population of viable micro-organisms on a product and/or a package

Note 1 to entry: In practical use, microbial cleanliness is often referred to as "bioburden".

3.5.2
cleanliness — particulate matter
freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact

3.6
infective agent
micro-organism that has been shown to cause surgical wound infections or that might cause infection in the patient, members of staff or other

3.7
surgical procedure
surgical intervention penetrating skin or mucosa, performed by a surgical team under controlled environmental conditions

3.8
aerosol
gaseous suspension of solid and/or liquid particles, the particles having a negligible falling velocity

Note 1 to entry: See EN 132.

Note 2 to entry: This velocity is generally considered to be less than 0,25 m/s.

3.9
filter
material used for mechanical and physical separation or deposition of aerosol particles (liquid or solid) from the inhaled and exhaled air

3.10
splash resistance
ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure

4 Classification

Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant.

5 Requirements

5.1 General

5.1.1 Materials and construction

The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness (absence of particulate matter).

5.1.2 Design

The medical face 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.

Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).

5.2 Performance requirements

5.2.1 General

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

5.2.2 Bacterial filtration efficiency (BFE)

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

5.2.3 Breathability

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

5.2.4 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.

5.2.5 Microbial cleanliness (Bioburden)

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

NOTE EN ISO 11737-1 specifies requirements and provides guidance for the enumeration and microbial characterisation of the population of viable microorganisms on or in a medical device, component, raw material or package.

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 µ 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.

5.2.6 Biocompatibility

According to the definition and classification in EN ISO 10993-1, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.

As a minimum, EN ISO 10993-5 and EN ISO 10993-10 shall be considered.

5.2.7 Summary of performance requirements

Table 1 — Performance requirements for medical face masks

Test	Type Ia	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm ²)	< 29,4	< 29,4	< 49,0
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30
a 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.			

6 Labelling and information to be supplied

Annex I, §13, of the Medical Devices Directive (93/42/EEC) specifies the information that has to be specified on the packaging in which the medical face 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).

EN ISO 15223-1 and EN 1041 should be considered.

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. 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 medical face masks intended to be used in operating rooms and health care settings with similar requirements are designed to protect the entire working environment. This standard describes two types of medical face masks with associated protection levels. As a minimum, Type I medical face masks are used for patients in order to reduce the risk of the spread of infections, particularly in epidemic or pandemic situations. Type II masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements.

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 and particles that are created in the surgical environment, e.g. by the use of electro-cautery devices.

If the intended use of the mask is to protect the wearer against infective agents (bacteria, viruses or fungi), the use of a respirator device should be considered. Performance requirements for respirators are the scope of EN 149.

The level of efficiency offered by a mask depends on a number of factors such as the filtration efficiency, quality 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 characterise 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 medical face 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 General

B.2.2 and B.2.3 describe commercially available solutions of tryptic soy agar and tryptic soy broth. Other variants may be suitable.

B.2.2 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

B.2.3 Tryptic soy broth

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

B.2.4 Peptone water

Formula/liter

Peptone	10 g
Sodium chloride	5 g
Final pH	7,2 ± 0,2 at 25 °C

B.2.5 Culture of *Staphylococcus aureus* ATCC 6538, growing on tryptic soy agar slants**B.3 Apparatus****B.3.1 Six stage cascade impactor**

B.3.2 Nebulizer, capable of delivering particles with a mean size of $(3,0 \pm 0,3) \mu\text{m}$ when in contact with the impactor

B.3.3 Aerosol chamber, glass, 600 mm long and 80 mm in external 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 representative areas to incorporate all/any variation in construction. Unless otherwise specified, the testing shall be performed with the inside of the medical face mask in contact with the bacterial challenge.

Each test specimen shall be conditioned at $(21 \pm 5) ^\circ\text{C}$ and $(85 \pm 5) \%$ relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.

B.5 Preparation of bacterial challenge

Staphylococcus aureus (see 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 $(37 \pm 2) ^\circ\text{C}$ for (24 ± 2) h. The culture shall then be diluted in peptone water to give a concentration of approximately 5×10^5 cfu/ml.

The bacterial challenge shall be maintained at $(2\,200 \pm 500)$ 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 $(3,0 \pm 0,3) \mu\text{m}$ (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 $(37 \pm 2) ^\circ\text{C}$ for (48 ± 4) h.

B.6.9 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 (stages 3 to 6). 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.

B.7 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.

B.8 Test report

The following information shall be given in the test report;

- a) number and date of this European Standard;
- b) lot number or batch code of the masks tested;
- c) dimensions of the test specimens and the size of the area tested;
- d) which side of the test specimen was facing towards the challenge aerosol;

¹⁾ See the positive hole conversion table found in the Andersen sampler user manual.

- e) flow rate during testing;
- f) mean of the total plate counts of the two positive controls;
- g) mean plate count of the negative controls;
- h) bacterial filtration efficiency for each test specimen.

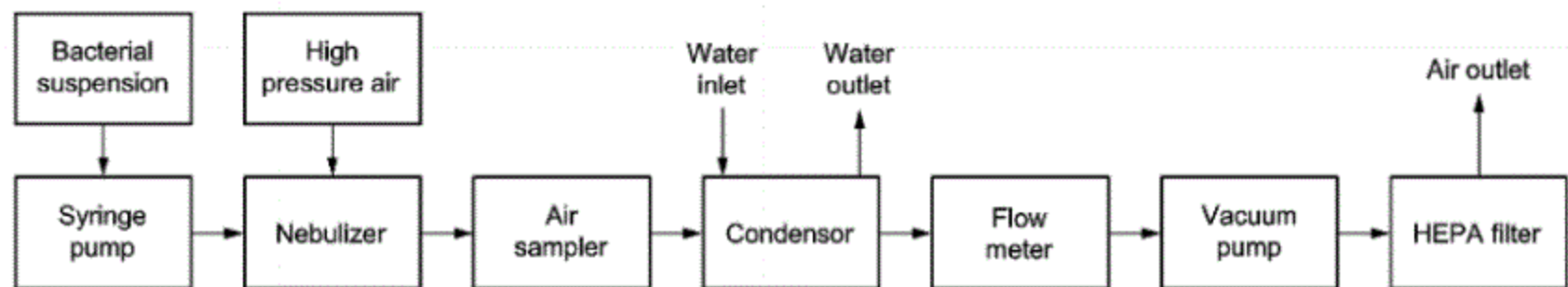
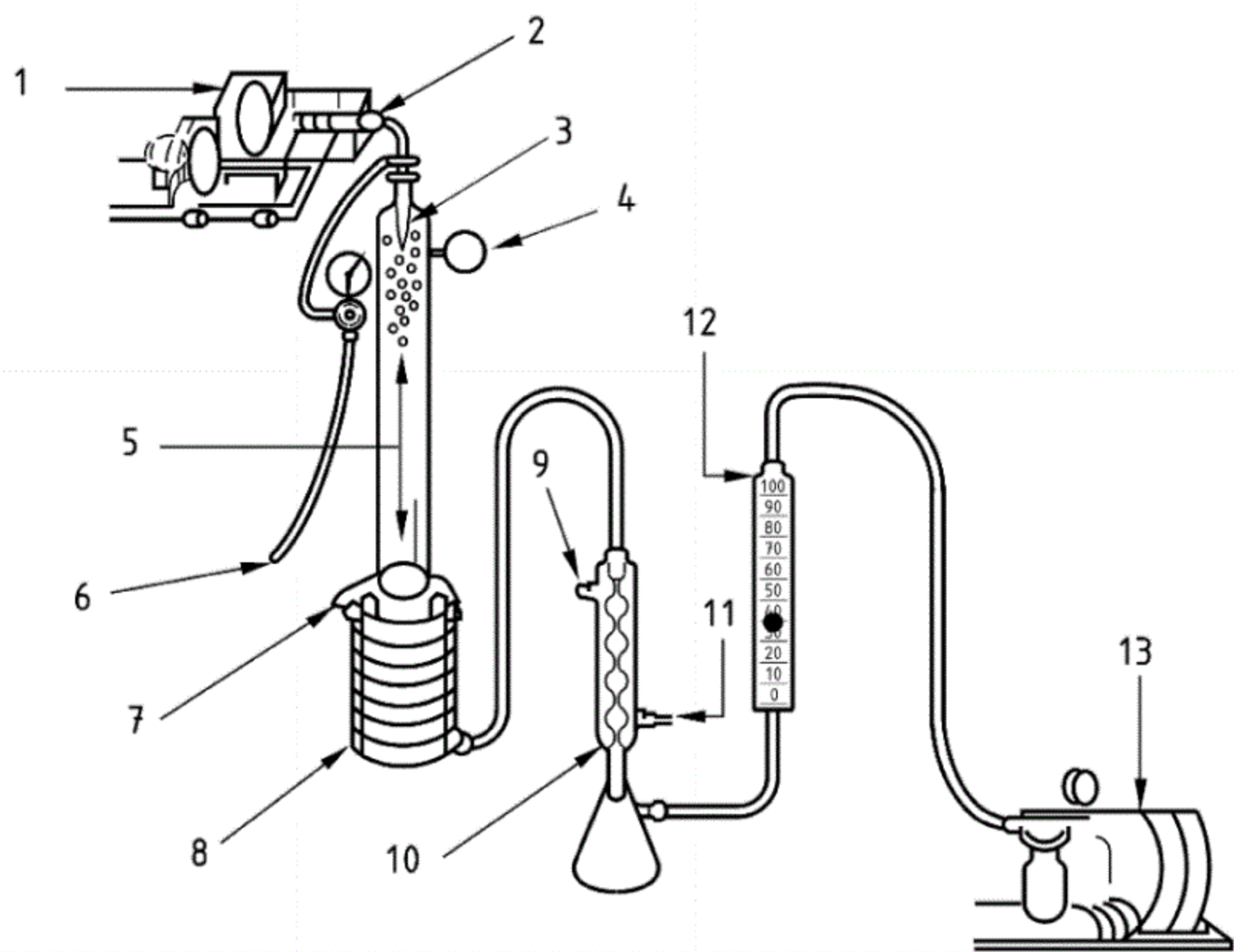


Figure B.1 — Principle of BFE test apparatus



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 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 C.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.

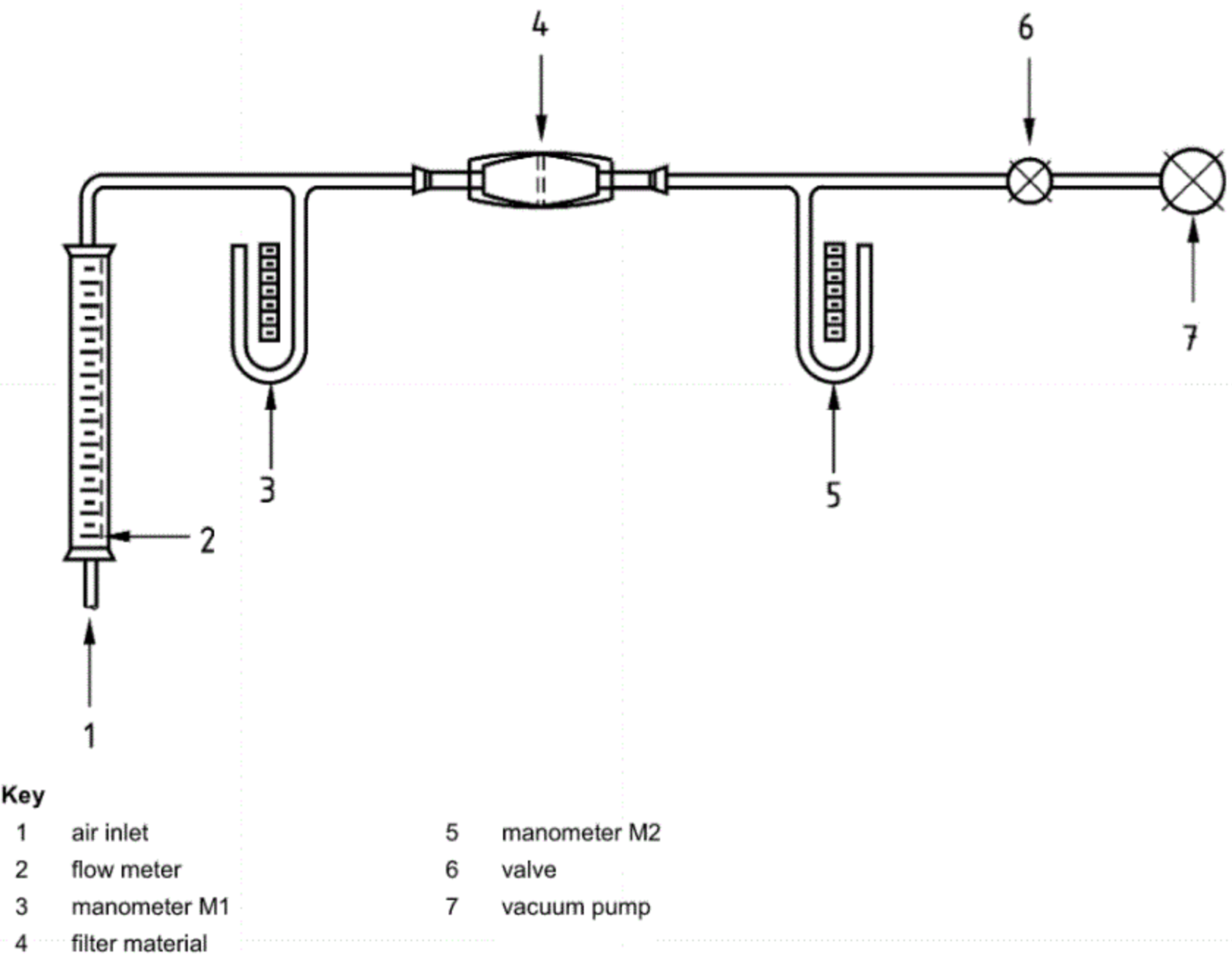


Figure C.1 — Apparatus for measuring air resistance

C.2 Apparatus

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

C.2.2 Manometers, M1 and M2 or differential manometer

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. If one specimen cannot provide 5 test areas of 2,5 cm in diameter, the number of test areas retrieved should be representative for the entire mask. The number of specimens that shall be tested is minimum 5, 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.

Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.

C.4 Procedure

C.4.1 The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm²) 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.

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 5 (or appropriate number of) different areas of the mask and the readings averaged.

C.5 Calculation of differential pressure

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

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

where

- 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 cm² area of the test material;
- ΔP is the differential pressure per cm² of test material expressed in Pa.

C.6 Test report

The following information shall be given in the test report:

- a) number and date of this European Standard;

- b) lot number or batch code of the masks tested;
- c) flow rate during testing;
- d) differential pressure for each test specimen.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

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

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

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

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.2.3, 6	8.1	
5.2.2	9.2	
6	13	

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

Bibliography

- [1] EN 132, *Respiratory protective devices - Definitions of terms and pictograms*
- [2] EN 149, *Respiratory protective devices — Filtering half-masks to protect against particles — Requirements, testing, marking*
- [3] EN 1041, *Information supplied by the manufacturer of medical devices*
- [4] EN 1174 (all parts), *Sterilisation of medical devices — Estimation of the population of micro-organisms on product*
- [5] EN ISO 15223-1, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1)*
- [6] 93/42/EEC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by DIRECTIVE 2007/47/EC of the European Parliament and of the Council of 5 September 2007
- [7] ISO 139, *Textiles — Standard atmospheres for conditioning and testing*