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## 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 29 December 2024.

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## European foreword

This document (EN 14683:2025) 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of an identical text or by endorsement, at the latest by July 2025, and conflicting national standards shall be withdrawn at the latest by July 2025.

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

This document supersedes EN 14683:2019+AC:2019.

EN 14683:2025 includes the following significant technical changes with respect to EN 14683:2019+AC:2019:

- a) the terms “processor”, “reusable product”, “single-use product” and “transparent medical face mask” have been added to Clause 3;
- b) the Clause “Design” has been amended, first to clarify that requirements for additional features to medical face masks are not specified in this document and secondly to include transparent medical face masks;
- c) the requirements on microbial cleanliness (bioburden) have been specified in more detail;
- d) the unit of differential pressure has been changed to Pa;
- e) A new Clause 6 on “Manufacturing and processing requirements and documentation” has been added;
- f) Annex A “Information for users” has been completely revised;
- g) Annex B “Method for *in vitro* determination of bacterial filtration efficiency (BFE)” has been further specified in regard to the use of the six-stage cascade impactor;
- h) Annex C “Breathability – Method for determination of the differential pressure” has been completed with a formula for the calculation of the airflow, when a different test area is used than the circular test area of 25 mm in diameter (C.4.5);
- i) the option to use AQL for sample numbers in Annex B and Annex C has been removed;
- j) Annex D “Test procedure for microbial cleanliness” has been completely revised;
- k) a new informative Annex E “Rationales” has been added to provide a concise rationale for the important requirements of this document. It includes information on the proposed removal of Type I products in the next revision;
- l) a new informative Annex F “Transparent medical face masks” has been added;
- m) a new informative Annex G “Environmental impact” has been added;
- n) alignment with Regulation (EU) 2017/745 (including updated Annex ZA);
- o) update of normative references and bibliography.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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



## Introduction

Medical face masks can be used as part of an infection control chain. The main intended use of medical face masks is to protect patients by attenuating the spread of larger particles from the wearer's mouth and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids. 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.

Bypass leakage around the medical face mask can affect the particle attenuation ability of medical face masks, especially for smaller particles.

Besides the normative annexes, the following informative annexes are included:

- Annex A provides information for the users of medical face masks;
- Annex D provides a test procedure for microbial cleanliness;
- Annex E provides a concise rationale for the important requirements of this document and is intended for use by those who are familiar with the subject of this document but who have not participated in its development;
- Annex F provides some recommendations on transparent medical face masks (TMFM);
- Annex G provides some information to enable the transformation to a circular economy. This included material efficiency – the conservation of materials by making products more durable, resource-efficient and which facilitates the reuse or recycling of parts and/or materials at the end of life.

Standards for face masks for use as respiratory personal protective equipment are available (e.g. EN 149:2001+A1:2009).

Technical Committee CEN/TC 205 “Non-active medical devices” proposes to remove the specification for Type I medical face masks at the next revision of this document. The reasons for doing this are documented in Annex E. Therefore, CEN/TC 205 encourages healthcare organizations and agencies to consider the potential impact on their guidance of this change.

## 1 Scope

This document 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 document is not applicable to face masks intended exclusively for the personal protection of staff. Compliance with this standard does not demonstrate compliance with the requirements of the relevant PPE regulations.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 10993-1:2020, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)*

EN ISO 11737-1:2018,<sup>1</sup> *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)*

ISO 22609:2004, *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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp/>
- IEC Electropedia: available at <https://www.electropedia.org/>

### 3.1

#### **aerosol**

gaseous suspension of solid and/or liquid particles

### 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

#### **biocompatibility**

quality of being accepted in a specific living environment without adverse or unwanted side effects

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<sup>1</sup> As impacted by EN ISO 11737-1:2018/A1:2021.

**EN 14683:2025 (E)****3.4****colony forming unit****CFU**

unit by which the culturable number of microorganisms is expressed

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

**3.5****differential pressure**

air permeability of the medical face mask, measured by determining the difference of pressure across the medical face 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 medical face mask.

**3.6****filter**

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

**3.7****infective agent**

microorganism that has been shown to cause surgical wound infections or that might cause infection in the patient, members of staff or other persons

**3.8****medical face mask**

surgical mask

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

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

**3.9****microbial cleanliness**

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”.

**3.10****processor**

natural or legal person who processes products so that their performance complies with the requirements of this document

Note 1 to entry: A processor who places a product on the market is a manufacturer in the sense of this document.

Note 2 to entry: A processor of reusable products is often referred to as a ‘reprocessor’ and processing reusable products is often referred to as ‘reprocessing’ (as e.g. in Medical Device Regulation (EU) 2017/745).

**3.11****reusable product**

product intended by the manufacturer to be reprocessed and reused



**3.12****single-use product**

product that is intended to be used on one individual during a single procedure

**3.13****splash resistance**

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

**3.14****transparent medical face mask****TMFM**

medical face mask with a transparent section that allows the mouth and some facial expressions to be seen

Note 1 to entry: The design of a transparent medical face mask can facilitate communication not only to those dependent on lip reading but also individuals with cognitive impairments. Audio-visual cues can also improve speech intelligibility in people with no hearing impairment.

Note 2 to entry: A medical face mask with a visor attachment covering the eyes only is not regarded as a transparent medical face mask.

## **4 Classification**

Medical face masks specified in this document 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 medical face mask is splash resistant. The 'R' signifies splash resistance and the Type is marked "IIR".

## **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 material. 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 and safety with regards to the release of potentially hazardous substances or particulates.

To comply with this document, products shall meet all the requirements specified in this document throughout their useful life.

#### **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 when in use and which ensures that the medical face 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). The requirements for such additional features are not specified in this document.

The function of transparent medical face masks and their performance requirements are set out in Annex F.

NOTE Medical face masks designed in accordance with this document are not expected to seal tightly to the face. In the absence of a quantitative bypass leakage assessment, the total leakage is not well defined.

## 5.2 Performance requirements

### 5.2.1 General

All tests shall be carried out on finished products or samples cut from finished products.

### 5.2.2 Bacterial filtration efficiency (BFE)

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

For thick and rigid medical face masks such as rigid duckbill or cup masks the test method might not be suitable as an effective seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.

When a medical face mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete medical face mask.

### 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.

If the use of a respiratory protective device as face 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 document. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).

### 5.2.4 Splash resistance

When tested in accordance with ISO 22609:2004 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.

All tests shall be undertaken with the targeting plate.

### 5.2.5 Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1:2018 the bioburden of the medical face mask shall be  $\leq 30$  CFU/g tested (see Table 1).

NOTE EN ISO 11737-1:2018 specifies requirements and provides guidance for the enumeration and microbial characterization of the population of viable microorganisms on or in a medical device, component, raw material or package.

To determine the medical face mask's bioburden according to EN ISO 11737-1:2018, the test procedure as described in Annex D can be used.

The number of medical face masks that shall be tested is minimum 5 of the same batch/lot. Medical face mask samples for testing should be provided in the original primary packaging (dispenser box or equivalent) as offered to the end user. When 5 samples are selected take the top, bottom and 3 randomly chosen medical face masks. If the medical face mask contains a visor or other accessories, it should be included in the testing.

Other test conditions (extraction procedure) as described in EN ISO 11737-1:2018 may be applied, but to be in line with the limits given in Table 1, the media and incubation time should be as follows:

- Tryptic Soy Agar (TSA) for total viable aerobic microbial count – Incubation for 3 days at  $(30 \pm 2)$  °C;
- Sabouraud Dextrose Agar (SDA) with chloramphenicol for fungi – Incubation for 7 days at  $(20$  to  $25)$  °C.

Extraction efficiency shall be checked and the correction factor shall be applied to the final count.

The extraction procedure shall be documented in the test report.

The microbial cleanliness (bioburden) expressed in CFU/g is obtained by addition of the total TSA count and total SDA count, divided by the total mass of the medical face mask.

In the test report, indicate the total bioburden per individual medical face mask and based on the mass of the medical face mask, the total bioburden per gram.

### 5.2.6 Biocompatibility

The medical face mask shall be evaluated according to EN ISO 10993-1:2020. The applicable toxicology testing regime shall be determined, if necessary. Both direct (skin and mucosa) and indirect (through the inhaled air) contact should be considered. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The biocompatibility evaluation shall be available upon request.

### 5.2.7 Summary of performance requirements

Each test specimen's result shall meet the performance requirements of Table 1 except for splash resistance pressure where a minimum of 29 specimens out of 32 shall pass the test.

**Table 1 — Performance requirements for medical face masks**

Test	Type I <sup>a</sup>	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa) <sup>b</sup>	≤ 200	≤ 200	≤ 300
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 medical face masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements. <sup>b</sup> The unit for differential pressure has changed in this revision. Further details can be found in E.5.			

## 6 Manufacturing and processing requirements and documentation

**6.1** It shall be documented that the requirements of this document are met and that the fitness for the intended purpose has been established for each use, both for single-use and reusable medical devices.

Reprocessing of reusable medical face masks shall be undertaken under an appropriate quality management system, which includes requirements for processing and life-cycle control. A quality system such as EN ISO 13485:2016<sup>2</sup> is recommended, and EN 14065:2016 may also be considered.

<sup>2</sup> As impacted by EN ISO 13485:2016/AC:2018 and EN ISO 13485:2016/A11:2021.

**6.2** For reusable products, the processor shall be provided with validated information on the number of reuses and reprocessing cycles based on standardized processes, together with information on measures for maintaining the technical and functional safety of the medical device and packaging.

## **7 Marking, labelling and packaging**

The following information shall be included on the packaging in which the medical face mask is supplied:

- a) the standard number of this document;
- b) the type of medical face mask (as indicated in Table 1);
- c) an indication of which side of the mask shall be in contact with the face.

**NOTE** Annex I, section 23 of the Medical Device Regulation (EU) 2017/745 gives additional information to include on the packaging. This information is considered mandatory by the Regulation.

The manufacturer can also indicate the size of the medical face mask on the packaging.

EN ISO 15223-1:2021 and EN ISO 20417:2021 should be considered.



## **Annex A**

### **(informative)**

## **Information for users**

### **A.1 Selection and use**

Medical face masks, commonly referred to as surgical masks, are designed to attenuate the emission of larger droplets from the wearer. However, they are less effective at attenuating the emission of smaller aerosols, due to the fit and facial seal. In a workplace setting, where a risk assessment identifies a risk of respiratory exposure due to an airborne hazard, personal protective equipment [CE marked to Regulation (EU) 2016/425] such as a respirator may be required. A medical face mask is not a respirator.

This document does not specify leakage performance requirements on the inward direction. Total inward leakage is often larger than total outward leakage for two reasons: the high velocity jet of the outward breath, leading to more impaction of particles than for the diffuse inward breath, and the rapid evaporation of particles after exhalation, making them smaller and harder to filter.

This document describes two types of medical face masks with associated performance levels. Type I is the most basic performance level. Type II and type IIR medical face masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements, and Type IIR medical face masks are also intended to protect the wearer against splashes of potentially contaminated fluids.

### **A.2 Donning and doffing**

Due to the fact that medical face masks are considered highly contaminated from use, it is essential that:

- the body of the medical face mask is not touched by the fingers/hands of the wearer;
- hands are disinfected (full hand disinfection) before donning and after removal of the medical face mask;
- the nose clip, if present, is fitted on and around the nose to improve the contact between the medical face mask and the face to reduce outward leakage;
- a medical face mask is worn covering the nose and mouth of the wearer;
- a used medical face mask should be disposed of or placed into suitable collection containers when no longer needed. Medical face masks should be changed between procedures.



## Annex B (normative)

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

#### B.1 General

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

#### B.2 Principle

A specimen of the medical face 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 medical face mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the medical face mask is given by the number of colony forming units prevented from passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol. For test apparatus, see Figure B.3.

#### B.3 Reagents and materials

##### B.3.1 General

B.3.2 and B.3.3 describe commercially available solutions of tryptic soy agar and tryptic soy broth. Other variants may be suitable.

##### B.3.2 Tryptic soy agar

###### Formula/litre

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.3.3 Tryptic soy broth

###### Formula/litre

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.3.4 Peptone water

#### Formula/litre

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

### B.3.5 Culture of *Staphylococcus aureus* ATCC 6538, growing on tryptic soy agar slants.

## B.4 Test apparatus

**B.4.1 Six-stage cascade impactor**, the arrangement is specified in Table B.1. The use of plastic Petri dishes is permitted but their dimensions should be as close as possible to the dimensions of the glass dishes for which the impactor is designed [14]. The agar-to-grid distance for each stage of the impactor is also very important. The volume of agar should be determined according to the type of Petri dishes selected. A volume of 27 ml is generally recommended for the glass dishes offered with the Andersen impactor. The volume used with the selected Petri dishes should give an agar-to-grid distance comparable to that obtained with a reference glass dish filled with 27 ml of agar or the volume mentioned by the supplier.

**B.4.2 Nebulizer**, capable of delivering particles with a mean size of  $(3,0 \pm 0,3) \mu\text{m}$  when in contact with the cascade impactor.

**B.4.3 Aerosol chamber**, glass,  $(600 \pm 5)$  mm long and  $(80 \pm 5)$  mm in internal diameter.

**B.4.4 Flow meters**, capable of measuring a flow rate of 28,3 l/min.

**B.4.5 Pressure gauge**, capable of measuring a pressure of 35 kPa to a tolerance of  $\pm 1$  kPa.

**B.4.6 Erlenmeyer flasks**, 250 ml and 500 ml capacity.

**B.4.7 Peristaltic or syringe pump**, capable of delivering 0,01 ml/min.

**B.4.8 Vacuum pump**, capable of maintaining a flow rate of 57 l/min.

## B.5 Test specimens

Test specimens shall be cut from complete medical face masks. A complete medical face mask may be used in place of a cut specimen, as long as the extremities are removed, the medical face mask is laid flat and all layers are incorporated (in case of folded medical face masks unfold the mask in order to test a surface as flat as possible). Each specimen shall be minimum 100 mm × 100 mm and shall include all layers of the medical face mask in the order in which they are placed in the complete medical face mask. The number of specimens that shall be tested is minimum 5.

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 a minimum of 4 h to bring them into equilibrium with atmosphere prior to testing.

## B.6 Preparation of bacterial challenge

*Staphylococcus aureus* (see B.3.5) shall be inoculated into an appropriate volume of tryptic soy broth (TSB) (e.g. in 30 ml TSB in an Erlenmeyer flask) and incubated with mild shaking at a temperature of  $(37 \pm 2) ^\circ\text{C}$  for  $(24 \pm 2)$  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  $1,2 \times 10^3$  to  $3,5 \times 10^3$  CFU per test. The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see B.7.3) and the dilution of the challenge suspension adjusted accordingly. The mean particle size (MPS) in the bacterial challenge shall be maintained at  $(3,0 \pm 0,3) \mu\text{m}$  (see B.7.9).

**Table B.1 — Cascade impactor stage arrangement**

Stage number	1	2	3	4	5	6
Size of particle	P1	P2	P3	P4	P5	P6
Viable “particle” plate count	C1	C2	C3	C4	C5	C6

where

$$P1 = 7,00 \mu\text{m}$$

$$P2 = 4,70 \mu\text{m}$$

$$P3 = 3,30 \mu\text{m}$$

$$P4 = 2,10 \mu\text{m}$$

$$P5 = 1,10 \mu\text{m}$$

$$P6 = 0,65 \mu\text{m}$$

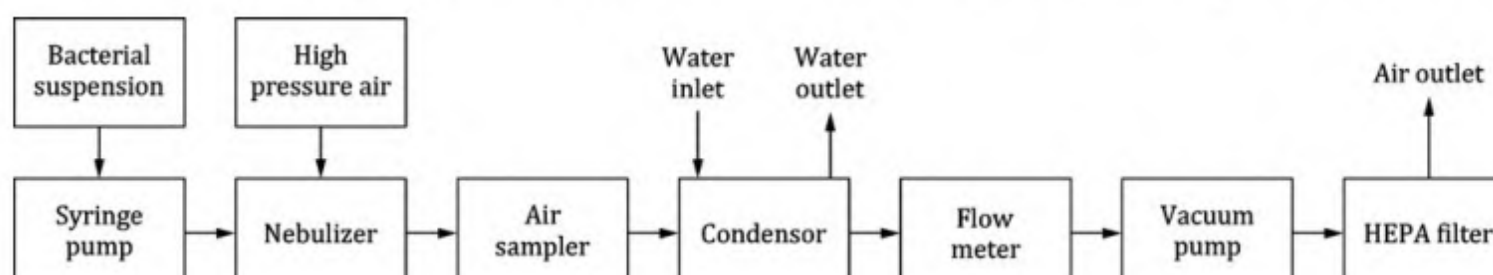
$$MPS = \frac{(P1 \times C1) + (P2 \times C2) + (P3 \times C3) + (P4 \times C4) + (P5 \times C5) + (P6 \times C6)}{C1 + C2 + C3 + C4 + C5 + C6} \quad (\text{B.1})$$

The viable “particles” plate count values used for MPS calculations are the converted “probable hit” counts calculated using the positive hole conversion chart from the cascade impactor manual.

The MPS value above is the 50 % effective cut-off diameter calculated for each stage using the formula and information from the cascade impactor manual.

## B.7 Procedure

**B.7.1** Assemble the test apparatus in accordance with the flow chart shown in Figure B.1 or Figure B.3.

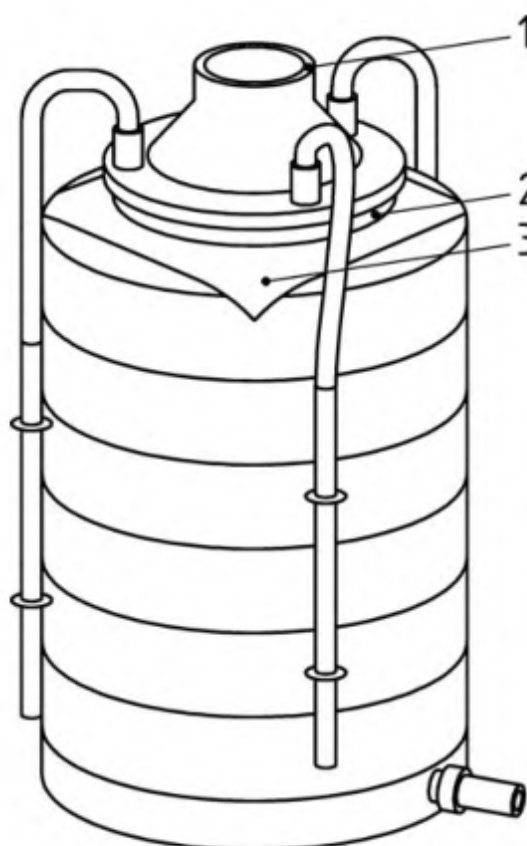


**Figure B.1 — Principle of BFE test apparatus**

**B.7.2** Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.

**B.7.3** 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 cascade impactor one additional minute (total test time is 2 min). Then remove the plates from the cascade impactor. Ensure that each plate is numbered to indicate its position in the cascade impactor.

**B.7.4** Place fresh plates in the cascade impactor, clamp the test specimen in place between the first stage of the cascade impactor and the inlet cone (see Figure B.2) and repeat the procedure described in B.7.3. The test area is determined by the inner diameter of the impactor lid (~40 cm<sup>2</sup>). Alternative means to position the sample may be appropriate, but, if deviated from the procedure, this shall be documented in the test report.



**Key**

- 1 inlet cone
- 2 o'ring inlet cone
- 3 cloth / medical face mask

**Figure B.2 — Placement of test specimen on the cascade impactor**

**B.7.5** Repeat this procedure for each test specimen.

**B.7.6** After the last test specimen has been tested, perform a further positive control run.

**B.7.7** Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.

**B.7.8** Incubate all the plates at  $(37 \pm 2) ^\circ\text{C}$  for (20 to 52) h.

**B.7.9** 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 cascade impactor. Use the “positive hole” conversion table<sup>3</sup> in accordance with the instructions of the cascade impactor manufacturer for 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 (MPS) of bacterial challenge aerosol using the formula given in B.6.

Some aggregates emanating from the same hole of the grid shall be counted as a single colony. If not, the count of the colonies can be overestimated, which could lead to a total count of colonies higher than 400 which is the number of holes of the grid.

## B.8 Calculation of bacterial filtration efficiency (BFE)

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

$$B = (C - T) / C \times 100 \quad (\text{B.2})$$

where

- $B$  is the bacterial filtration efficiency in percent;
- $C$  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.9 Test report

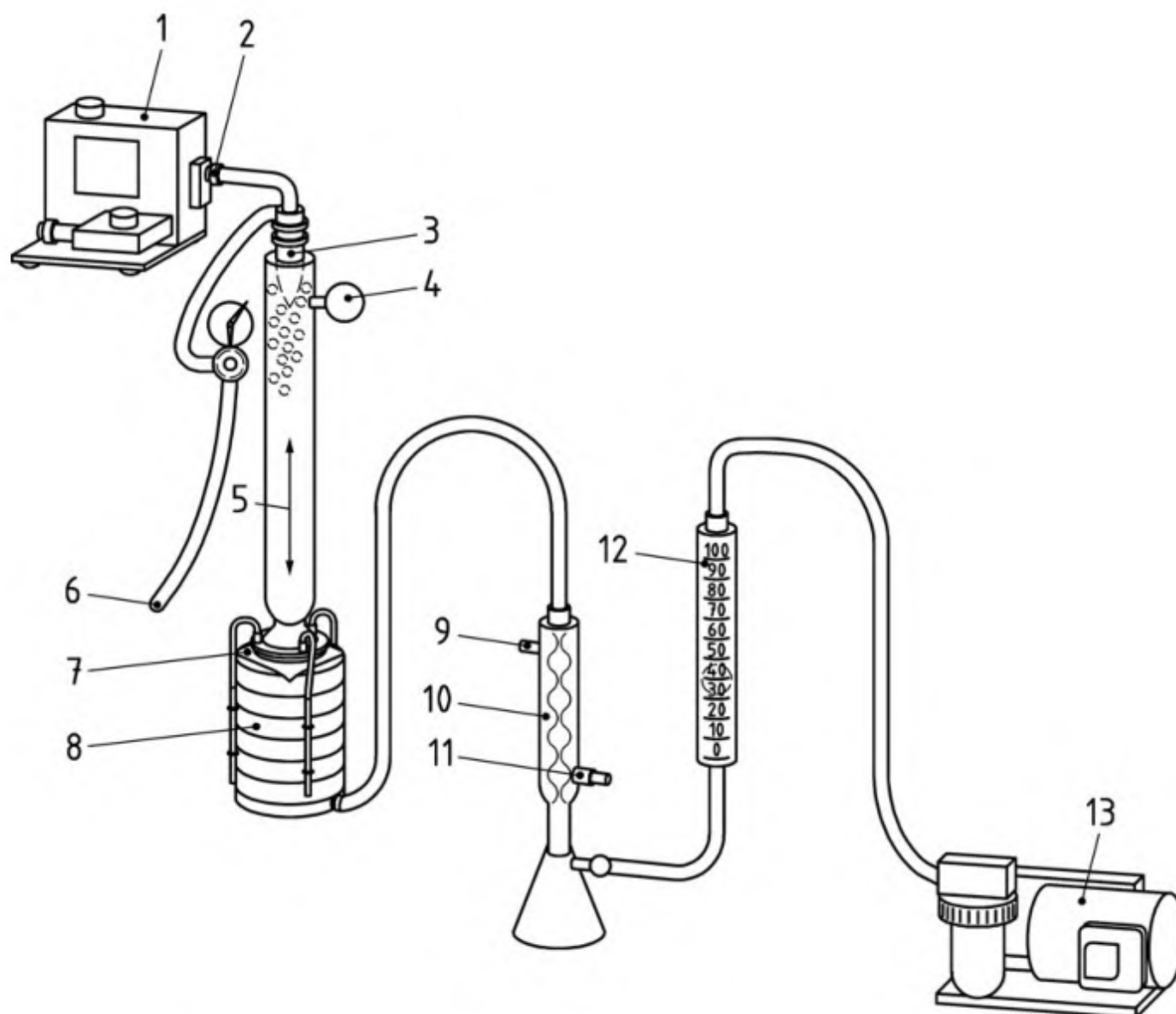
The following information shall be given at least in the test report:

- a) standard number and date of this document;
- b) information on the sample (incl. the lot number or batch code and the description of the medical face masks tested);
- c) the size of the area tested;
- d) which side of the test specimen was facing towards the challenge aerosol;
- 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 (BFE) for each test specimen (as calculated in B.8);
- i) any deviations from the procedure
- j) any unusual features observed;
- k) the date of the test.

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<sup>3</sup> See the positive hole conversion table found in the cascade impactor manual.



**Key**

- |   |                                  |    |                          |
|---|----------------------------------|----|--------------------------|
| 1 | drive mechanism                  | 8  | cascade impactor         |
| 2 | bacterial suspension             | 9  | outlet to sink           |
| 3 | nebulizer                        | 10 | condenser                |
| 4 | filter                           | 11 | cold water inlet         |
| 5 | aerosol chamber                  | 12 | calibrated flow meter    |
| 6 | tube to high pressure air source | 13 | compressor (vacuum pump) |
| 7 | test material                    |    |                          |

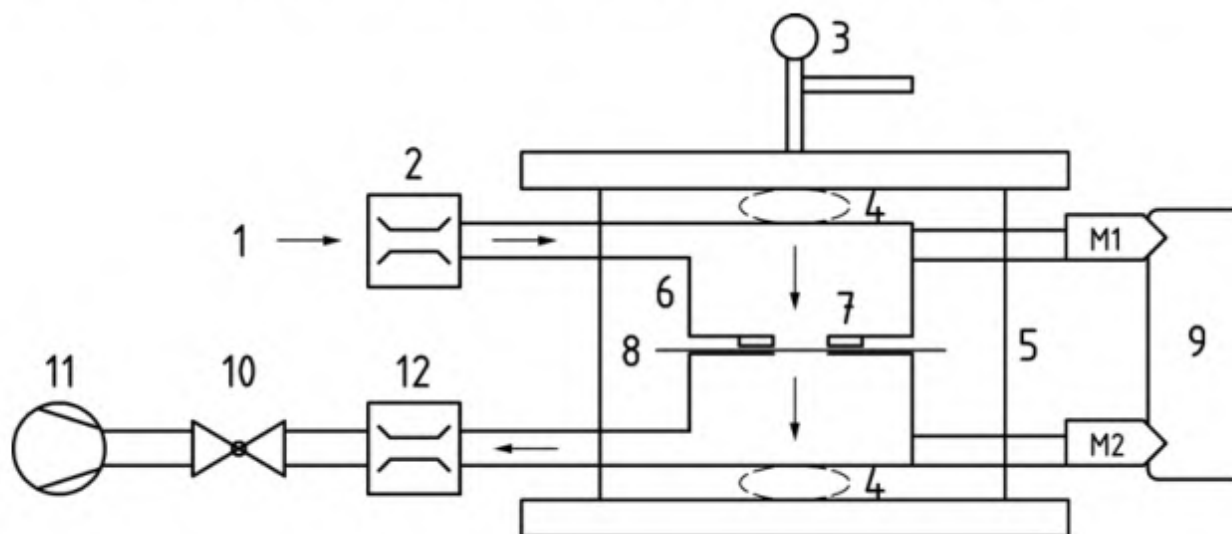
**Figure B.3 — Example of real BFE test apparatus**

## Annex C (normative)

### Breathability – Method for determination of the 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. A water-filled (or digital) differential manometer is used to measure the differential pressure. A mass flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the test apparatus and a needle valve is used to adjust the airflow rate.



#### Key

- |   |  |
|---|--|
| 1 air inlet   | 7 metallic ring (3 mm thick)                     |
| 2 mass flow meter   | 8 filter material                                |
| 3 lever for mechanical clamping   | 9 differential manometer or M1 and M2 manometers |
| 4 system for final adjustment of the pressure (either at the top or the bottom) | 10 valve   |
| 5 system ensuring optimal alignment of the 2 parts of the sample holder         | 11 vacuum pump including a pressure buffer tank  |
| 6 sample holder with a metal sealing mechanism                                  | 12 mass flow meter for checking leaks (optional) |

**Figure C.1 — Test apparatus for measuring differential pressure**

#### C.2 Test apparatus

**C.2.1 Mass flow meter(s)** capable of measuring an airflow of 8 l/min with an accuracy of  $\pm 1\%$  at full scale or  $\pm 0,15$  l/min.

**C.2.2 Manometer**, a differential manometer (water or digital) with an accuracy of  $\pm 0,5\%$  at full scale or  $\pm 4,98$  Pa. Individual manometers can also be used. M1 is for the upstream pressure measurement and M2 is for the downstream pressure measurement.

**C.2.3 Electric vacuum pump including a pressure buffer tank.**

#### **C.2.4 Valve permitting the adjustment of the flow rate.**

#### **C.2.5 Sample holder**

**C.2.5.1** The sample holder shall consist of a mechanical clamping system and alignment of the top and bottom holder.

**C.2.5.2** The sample holder shall consist of a mechanism to adjust the clamping pressure. A system with thread of screw can be used either at the bottom or top part of the sample holder.

**C.2.5.3** The internal diameter of the top holder and the bottom holder in the contact area with the filter material shall be  $(25 \pm 1)$  mm.

**C.2.5.4** The seal of the top and bottom holder onto the filter material shall consist of a metal-metal contact.

A metallic ring of internal diameter of  $(25 \pm 1)$  mm and circa 3 mm thick will be fixed to the top holder. The bottom holder will consist of a completely flat metallic surface with an internal diameter of  $(25 \pm 1)$  mm and a 3 mm area around the open diameter. Materials such as rubber or poly foam do not provide a sufficient seal and may deform into the test area.

**C.2.5.5** Validation of the test apparatus shall consist of a leak test. A second flow meter (12) placed immediately before the valve (10) will allow for evaluation of an air leak within the test apparatus. With the sample holder closed, start the pump and adjust the flow meter to read 8 l/min on the first flow meter (2). If no leaks are present both flow meters shall read 8 l/min.

Another check shall consist of stopping inlet air when both flow meters give 8 l/min. After a few seconds both flow meters shall indicate 0 l/min if no leaks.

### **C.3 Test specimens**

Test specimens are complete medical face masks or shall be cut from complete medical face masks. If a complete medical face mask is used, remove extremities and lay the medical face mask flat with all layers incorporated. Each specimen shall be able to provide different circular test areas of 25 mm in diameter. If one specimen cannot provide 5 test areas of 25 mm diameter, the number of test areas retrieved should be representative for the entire medical face mask. For thick and rigid medical face masks, the test method might not be suitable as a proper seal cannot be maintained in the sample holder. The number of specimens that shall be tested is minimum 5. All specimens tested shall be taken from areas representative from the medical face mask to incorporate all/any variation in construction. Unless otherwise specified, the testing shall be performed with the airflow direction from the inside of the medical face mask to the outside of the medical face mask.

Each test specimen shall be conditioned at  $(21 \pm 5)$  °C and  $(85 \pm 5)$  % relative humidity for a minimum of 4 h and tested either in the same conditions or at room temperature within 5 min of removal from the conditioning atmosphere.

### **C.4 Procedure**

**C.4.1** Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 l/min.

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**C.4.2** The holder is opened and the test specimen is placed across the 25 mm diameter orifice (total area 4,9 cm<sup>2</sup>) between the top and bottom parts of the holder. Then it is clamped in place using a mechanical clamp with sufficient pressure to avoid air leaks. Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.

With the specimen in place the flow rate should be 8 l/min as previously set in C.4.1. If the flow rate is not at 8 l/min, a leak can be present. Try to increase the pressure, if possible, to avoid this problem. In such case the use of a second flow meter during testing is also indicated.

**C.4.3** The differential pressure is read directly if using a differential pressure manometer. If using manometers M1 and M2 read and record each pressure.

**C.4.4** The procedure described in steps C.4.1 to C.4.3 is carried out on 5 different areas of the medical face mask and the readings averaged. If it is not possible to sample 5 test areas from each test specimen (for example, because the mask is too small), then fewer test areas shall be tested and the readings averaged.

If the medical face mask comprises different material types in different areas, test an even number of the different areas. For example, the average should consist of 3 readings on the top portion of the medical face mask with material type A and 3 readings on the bottom portion of the medical face mask with material type B.

**C.4.5** If a different test area ( $S$ ) is used, then the airflow ( $Q$ ) can be calculated using the following formula

$$Q = \frac{3}{50} \times S \times v_a \quad (\text{C.1})$$

where

$Q$  is the airflow, expressed in l/min;

$S$  is the applied test area, expressed in cm<sup>2</sup>;

$v_a$  is the air velocity, expressed in cm/s. Here,  $v_a = 27,2$  cm/s.

## **C.5 Calculation of differential pressure**

For each test material calculate the differential pressure  $\Delta P$  of each tested area as follows:

$$\Delta P = (X_{m1} - X_{m2}) \quad (\text{C.2})$$

where

$X_{m1}$  is the pressure in Pa, measured by manometer M1 – low pressure side of the material;

$X_{m2}$  is the pressure in Pa, measured by manometer M2 – high pressure side of the material;

$\Delta P$  is the differential pressure of test material expressed in Pa.

**NOTE** If a differential manometer is used the differential pressure ( $X_{m1} - X_{m2}$ ) is directly obtained.

## **C.6 Test report**

The following information shall be given at least in the test report:

- a) standard number and date of this document;
- b) information on the sample (incl. the lot number or batch code and description of the medical face masks tested);
- c) number and general location of the areas of the medical face mask the differential measurements were taken;
- d) flow rate and test area used during testing;
- e) differential pressure for each tested area of the test specimen and the average value for each test specimen. The average value for each test specimen is used to determine the final classification of the medical face mask (as calculated in C.5);
- f) any deviations from the procedure;
- g) any unusual features observed;
- h) the date of the test.



## Annex D (informative)

### Test procedure for microbial cleanliness

Weigh each medical face mask prior testing. The full medical face 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 and 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]) but other extraction fluids mentioned in the EN ISO 11737-1:2018 can be used.

The bottle is placed 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 µm 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 to 25) °C for TSA and SDA plates respectively.

To bring the count to the whole extract and indeed the whole medical face mask the count obtained on each plate (TSA and SDA with chloramphenicol) shall be multiplied by 3.

Also apply the correction factor obtained when checking the extraction efficiency.

The total bioburden (CFU/g) is calculated with the following formula:

$$3 \times CF \times (TSA + SDA) / M \quad (D.1)$$

where

*TSA* is the Tryptic Soy Agar, expressed in counts/100 ml;

*SDA* is the Sabouraud Dextrose Agar, expressed in counts/100 ml;

*CF* is the bioburden correction factor from the extraction efficiency experiments (see EN ISO 11737-1:2018, Annex C);

*M* is the mass of the medical face mask, expressed in g.

## **Annex E**

### **(informative)**

## **Rationales**

### **E.1 General**

This annex provides a concise rationale for the important requirements of this document and is intended for use by those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered essential for its proper application. Furthermore, as clinical practices and technologies change, it is believed that rationales for the present requirements will facilitate any revisions of this document necessitated by those developments.

### **E.2 Sizing of medical face masks**

There are no performance requirements regarding medical face mask sizing in this document, because there is no agreed range of sizes or dimensions in this industry. This revision does, however, introduce new text in Clause 6 which allows manufacturers to indicate the size of the medical face mask on the packaging in which the medical face mask is supplied.

### **E.3 Leakage around the medical face mask**

Whilst leakage around the medical face mask is acknowledged to be a performance parameter of interest, at present there is no suitable validated method which the Working Group is aware of. If such methods become available before the next revision the Working Group will consider them for inclusion.

### **E.4 Shelf life determination**

This document does not include any specific requirements for shelf life determination. However, medical face masks should comply with the requirements of this document until the end of their stated shelf life provided they are stored according to the instructions supplied by the manufacturer. The Working Group recommends that manufacturers test the properties of the medical face mask that are reasonably expected to alter over the shelf life of the product.

Since it is impracticable to complete real time ageing studies before introducing products to the market, accelerated stability studies based on kinetic principles can be used to assign a provisional shelf life. Such provisionally assigned shelf lives should be verified by real time studies.

### **E.5 Why does the document only test the filter using bacteria rather than viruses?**

Transmission of airborne infectious diseases takes place via droplets and aerosols. The viruses and bacteria are contained within these droplets and aerosols. Both usually require a film of fluid to encapsulate them once they leave the body to be able to infect another person and to remain viable.

The respiratory tract and skin around the mouth is a source of particles that can contain microorganisms. The particles emitted from the lower airway during breathing are typically smaller than 5 µm, whilst those emitted from the larynx and pharynx during speech are in the range 5 µm to 15 µm. Particles generated in the mouth during speech are mostly larger than 15 µm [12]. The size of exhaled particles containing

microorganisms is influenced by the location in the respiratory tract from where they were aerosolised, not just the size of the microorganism itself.

The test method used in this document (Annex B) challenges the medical face mask with a test droplet “Mean Particle Size” (MPS) of  $(3,0 \pm 0,3) \mu\text{m}$ , and the actual aerodynamic size range of particles counted in the test method is  $0,6 \mu\text{m}$  to  $7,0 \mu\text{m}$  and above. Although viruses are usually much smaller than bacteria used in this document, the size range of the droplets in the test is larger than both and the test should give similar results with viruses or bacteria.

One of the participating laboratories working on the revision of EN 14683:2019+AC:2019 has reported that when testing identical medical face masks using bacteria and bacteriophage (a virus which is safe to use in the laboratory as its hosts are bacteria, not humans) the filtration efficiency results are similar [15].

This means there is currently no evidence available to show a benefit to using viruses/bacteriophage to test medical face masks, as similar results would be expected using bacteria.

Overall, it is the aerosol droplet particle size which affects the filtration efficiency results and not the size of the microorganism carried inside the droplet.

## E.6 Breathability as determined by the differential pressure

The previous revision of this document had a mathematical error in how the differential pressure was calculated. This has been corrected in the new revision and has the effect of changing the units used for the test in Annex C and the limits for the medical face masks in Table 1.

Previously this document divided Pascals by the test area, which didn’t make sense as the Pascal is already a unit based on pressure per area ( $\text{N}/\text{m}^2$ ). The change means that the units are now a standard SI unit ( $\text{Pa}$  rather than  $\text{Pa}/\text{cm}^2$ ) and the limits have been multiplied by the test area ( $4,9 \text{ cm}^2$ ) to revert to standard SI units (rounded up, for example  $196 \text{ Pa}$  has been rounded to  $200 \text{ Pa}$ ).

This change has no practical effect on the performance of the medical face masks or the pass/fail limits of the test. Manufacturers can still compare medical face masks tested to the previous edition of this document by multiplying their old test results by 4,9.

The crucial testing parameter is the application of the air velocity at  $27,2 \text{ cm/s}$ . This value of air velocity ( $27,2 \text{ cm/s}$ ) is calculated from the application of an air flow of  $8 \text{ l/min}$  through a test area of  $4,9 \text{ cm}^2$  (corresponding to the  $25 \text{ mm}$  diameter orifice) as stated in EN 14683:2019+AC:2019, Annex C. The air velocity of  $27,2 \text{ cm/s}$  is retained in this document.

## E.7 Where did the limits in this document come from?

Most of the performance limits in this document are based on expert consensus at the time this document was initially developed, informed by the performance of products which were already being used in healthcare and which were believed to provide appropriate levels of protection and reflect the state of the art at the time.

## E.8 Bypass leakage

The loose fit of medical face masks ensures that a portion of the wearer’s breath bypasses the filter material by leaking around the edges of the medical face mask. The airstream which bypasses the material is forced to change direction abruptly. Smaller particles can follow the airstream and escape to the environment whilst larger particles will tend to deposit by impaction on the filter or the user’s face. For this reason there is little bypass of particles larger than  $10 \mu\text{m}$ , however the value of this threshold depends on many factors [13].



The total leakage of particles smaller than approximately 10 µm is therefore determined mainly by how closely the medical face mask fits to the face and its breathing resistance, rather than the filtration of the material. A looser fit and higher breathing resistance results in more leakage around the side of the medical face mask. The bypass leakage of smaller particles can substantially reduce the effectiveness of the medical face mask.

## E.9 Design

The filtration capacity of medical face mask materials can vary depending on the filter media. The fit of medical face 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 those with nose clamps that can be shaped to the wearer's nose. The difference in performance of different designs should be considered.

It is usual to characterize medical face mask performance using *in vitro* tests of the material from which the medical face mask is made. It is, however, important to consider the fit of the medical face mask carefully when a medical face mask for a certain application is chosen. A further factor to be considered during design is the resilience to the moisture in the wearer's breath.

## E.10 Proposed withdrawal of Type I medical face masks

The project group (PG) of CEN/TC 205/WG 14 "Surgical clothing and drapes, and medical face masks" who is responsible for this document intends to remove the Type I medical face mask from the next revision of this document unless there is a convincing reason to allow it to remain.

The reasons for the proposed removal are threefold:

1. The PG believes that there is sometimes confusion about the appropriate use of the Type I medical face mask (some PG members experienced this during the Covid 19 pandemic). In particular, because the Type I medical face mask is specified in a standard that is harmonized with the Medical Device Regulation (MDR), some think it is appropriate for medical staff to wear, even though this document explicitly states the following:

*"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 medical face masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements."*

The PG does not think that this information is always understood, leading to the potential misuse of Type I medical face masks.

2. During the Covid 19 pandemic, a number of initiatives were undertaken to develop alternative products to prevent transmission, such as the European Technical Specification for community face coverings (CEN/TS 17553:2022) which are intended for use by the general public in order to reduce the risk of droplet/aerosol projection towards nearby people, plus work presently underway by CEN/TC 205/WG 17 "Infection protection masks" on a combined infection prevention and personal protective device. The PG is of the view that these products, when available, can replace the use of Type I medical face masks depending on the circumstances of use.
3. Some manufacturers claim that their Type I medical face masks are identical to their Type IIR medical face masks apart from the fact that they don't have them tested for splash resistance. If correct, this would mean that there would not be a significant impact on Type I medical face mask manufacturers. The PG also believes that the market for Type I medical face masks in Europe is very small.

The PG appreciates that certain guidance documents which were relied on during the Covid 19 pandemic (such as the WHO "Mask use in the context of COVID-19" from December 2020) recommends

the use of Type I medical face masks for healthcare workers if Type II are not available. The WHO guidance states:

*"In case of stock outs of type II or higher medical masks, health workers should use a type I medical mask as an alternative."*

To allow time for these guidance documents to be updated with alternatives to the Type I medical face mask, the PG has agreed to wait until the next revision of this document to withdraw the Type I medical face mask.

Therefore, by the time the next revision of this document is due, the PG thinks that there will be suitable alternatives to Type I medical face masks available, as well as sufficient time for organizations to amend their advice to take into account the withdrawal of Type I medical face masks and the availability of community face coverings and infection prevention devices as noted above.

**Health Care Agencies and Organisations' guidance should be amended to take these developments into account.**

The PG would be interested to know if the proposed withdrawal would cause any insurmountable problems. Please inform the committee secretariat if this is the case, by contacting the secretariat of CEN/TC 205/WG 14 (by email to: [info@din.de](mailto:info@din.de)). The PG would take any concerns raised into consideration during the next revision cycle.

## **E.11 Removal of AQLs in Annex B and Annex C**

The previous edition of this document allowed the use of AQLs in both Annex B and C.

During the revision process, it was noted that very few testing laboratories were using the AQLs, and instead were using the fixed minimum number of samples specified in the Annexes.

The PG noted the concerns of both testing laboratories and manufacturers that testing to a 4 % AQL would entail very large increases in the numbers of samples tested. It was also noted that the previous editions did not give advice on the Inspection Level required, which has a significant effect on the numbers of samples to be tested. For example, for a batch of 20 000 masks, testing to General Inspection Level 1 would require the testing of 125 samples.

The PG discussed the options of using one of the "special inspection" levels, but instead decided to simplify the Annexes by reverting to the fixed number of samples, as in practice this is what the majority of test houses undertaking this work have used. There was general agreement from the test houses to clarify this.

It should be noted that although the use of AQLs has been removed for the purposes of determining compliance with the requirements of this document, this doesn't prevent manufacturers using the ISO 2859-1 sampling tables to determine their own sample sizes and AQLs for statistical process control.



## Annex F (informative)

### Transparent medical face masks

#### F.1 General

Transparent medical face masks (TMFM) can support communication by ensuring the mouth and facial expressions can be seen. This is of benefit not only to those dependent on lip reading but also individuals with cognitive impairments. Audio-visual cues can also improve speech intelligibility in people with no hearing impairment [see reference F1].

The minimum requirements for TMFM are still evolving. It is envisaged that a transparent medical face mask can provide similar performance to that required by this document with minor modifications to the test methods and requirements. In addition, there are several suggested design features described below, based on [see reference F2] and [see reference F3].

#### F.2 Breathability

As the material used for transparent windows is not permeable to air, the breathability and the filtration efficiency of transparent medical face masks is ensured by porous filter material surrounding the window. The breathability of the whole transparent medical face mask is calculated using the area-weighted harmonic average of the materials. This is proposed as a simpler method than testing a complete transparent medical face mask on a dummy as is required in [F3]. It should be possible with a sufficiently large filter area of sufficiently high breathability to achieve an equivalent whole transparent medical face mask breathability performance of a Type IIR medical face mask.

#### F.3 Differential pressure measurement of TMFM

Where a TMFM is composed of two materials, and one is impermeable, then the total differential pressure may be calculated from the following formula:

$$\Delta P_{tot} = \frac{\Delta P_1}{a_1} \quad (F.1)$$

Where  $\Delta P_{tot}$  is the adjusted total differential pressure in Pa,  $\Delta P_1$  is the differential pressure of the breathable material in Pa, and  $a_1$  is the proportional area of the breathable material which is calculated as follows:

$$a_1 = \frac{A_1}{A_{tot}} \quad (F.2)$$

where  $A_1$  is the area of the breathable portion in cm<sup>2</sup> and  $A_{tot}$  is the total area of the TMFM exposed to breath in cm<sup>2</sup> (which excludes straps and ties). For example, if the area of the breathable component is 120 cm<sup>2</sup>, and the total area of the TMFM is 240 cm<sup>2</sup>, then  $A_1$  is 0,5. If the  $\Delta P$  of the breathable material is 145 Pa, then  $\Delta P_{tot}$  is calculated to be 290 Pa.

If there are more than 2 materials, then in principle the differential pressure may be calculated as a harmonic mean below. It might not be possible to measure the differential pressure of impermeable materials, in which case it can be assumed to be infinite for this calculation.

$$\frac{1}{\Delta P_{tot}} = \frac{a_1}{\Delta P_1} + \frac{a_2}{\Delta P_2} + \frac{a_3}{\Delta P_3} + \dots \quad (F.3)$$

## F.4 Particle attenuation

Transparent medical face mask performance similar to a Type IIR medical face mask is ensured by achieving a breathability of the whole transparent medical face mask equivalent to at least a Type IIR medical face mask. The smaller area of filter material in TMFM leads to a greater pressure build up and higher velocity through the fabric. This decreases the filtration efficiency for small particles trapped by diffusion ( $\leq 1 \mu\text{m}$ ) and increases filtration for larger particles trapped by impaction ( $\geq 1 \mu\text{m}$ ). The transparent medical face mask's ability to reduce overall particle leakage is limited by the material bypass leakage, which is not measured in this document. As is the case for normal medical face masks, a lower breathability increases bypass, which increases the total leakage.

## F.5 Filtration measurement of TMFM

Impermeable materials cannot be tested for BFE as the test method is not appropriate for these materials. Instead the transparent material should be assumed to have a BFE of 100 %, and the overall BFE of the TMFM should be taken as the BFE of the material with the smallest measured BFE. If the transparent material is so thin that there is doubt over its impermeability, then the test method of EN ISO 22610:2006 (or comparable methods which assess microbiological permeability) can be used to check. However, in practice the consequence of minor leaks, through e.g. tiny pinholes, is probably small compared to the bypass leakage around the edges of the TMFM.

## F.6 Fit

The fit of the transparent medical face mask should not be worse than a normal medical face mask. The transparent medical face mask should remain in place whilst talking. This may require a more substantial retention mechanism than simple ear loops, such as a head harness, around the head ties, foam inserts and metal inserts which can aid shaping of the transparent medical face mask.

## F.7 Function

The transparent area of the transparent medical face mask should be large enough to ensure that facial expressions can be seen, not just the lips. There is no consensus yet on a minimum size. For example, it can be determined by practical testing with appropriate users.

## F.8 Condensation

Condensation will limit the visibility through the window and any drips can present a risk of infection to others. The design of the transparent medical face mask should ensure dripping is eliminated, and condensation is avoided by consideration of the airflow, pressure and temperature. The requirements for biocompatibility in 5.2.6 apply to any anti fogging agents used.

## F.9 Acoustics

The muffling of speech caused by transparent medical face masks can impede communication and in some cases it can negate the benefit of being able to see the mouth [see reference F4]. This is an evolving area and as such there is currently no requirement in this document for an assessment of the acoustic performance. However, acoustic performance can be improved by adjustment of such properties as mass and stiffness of the window and measuring the effect on the frequency response in the range of speech.

## F.10 Durability

The design and materials should be suitable for the intended duration of use. The join between the window and the filter material can be subject to higher levels of stress than the rest of the transparent medical face mask and may need special consideration.

Due to these limitations it is recommended that transparent medical face masks are used only when a clear benefit is indicated.

## F.11 Visibility

The transparent area shall comply with ISO 16321-1:2021, 7.13 (resistance to fogging of lenses or filters) [see reference F5]. If the product is single use, then omit the conditioning step in distilled water as required by ISO 18526-3:2020, 6.11.3 [see reference F6].

NOTE The conditioning step (immersion in water) will remove water soluble anti-fogging coatings, and whilst it is necessary for reusable visors (to ensure longevity of the coating between uses), is not considered necessary for single-use masks.

When examined by normal or corrected to normal vision, the transparent area shall allow the wearer's lips, mouth and areas of the face to be visible to others, as required for lip reading or other facial visibility requirements.

## F.12 References

- [F1] Yi, Hoyoung, Ashly Pingsterhaus, and Woonyoung Song. 'Effects of Wearing Face Masks While Using Different Speaking Styles in Noise on Speech Intelligibility During the COVID-19 Pandemic'. *Frontiers in Psychology* 12 (2021).  
<https://www.frontiersin.org/articles/10.3389/fpsyg.2021.682677>.
- [F2] [Withdrawn 2023-03-03] Transparent face mask technical specification  
<https://azuksappnpdsa01.blob.core.windows.net/datashare/Transparent-Mask-Specifications-November-2023.pdf>
- [F3] CEN/TS 17553:2022, *Textiles and textile products — Community face coverings — Minimum requirements, methods of testing and use*
- [F4] Brown, Violet A., Kristin J. Van Engen, and Jonathan E. Peelle. 'Face Mask Type Affects Audiovisual Speech Intelligibility and Subjective Listening Effort in Young and Older Adults'. *Cognitive Research: Principles and Implications* 6, no. 1 (18 July 2021): 49.  
<https://doi.org/10.1186/s41235-021-00314-0>
- [F5] ISO 16321-1:2021, *Eye and face protection for occupational use — Part 1: General requirements*
- [F6] ISO 18526-3:2020, *Eye and face protection — Test methods — Part 3: Physical and mechanical properties*



## **Annex G**

### **(informative)**

## **Environmental impact**

In 2015, the European Commission called on European standardization organizations such as CEN to develop standards to help enable the transformation to a circular economy. This included material efficiency - the conservation of materials by making products more durable, resource-efficient and which facilitates the reuse or recycling of parts and/or materials at the end of life.

The goal of this Annex is to encourage inventors, designers, procurement, manufacturers, reprocessors, recyclers and users to also include environmental considerations when designing, using, and disposing medical face masks, with the objective to minimize the environmental impact.

As this standard pertains to a high-volume product used for only a short period of time, end-of-life impacts such as disposal or reuse are particularly important.

The need to minimize the potential adverse impacts on the environment of any products/material and of their packaging which occur over the life cycle, is recognized, and increasingly regulated around the world.

Medical face masks, as with any other products, have an impact on the environment during all stages of their life cycle, e.g. extraction of resources; consumption of raw materials, water, and energy during production processes; emissions to water, soil, and air; and distribution and storage methods. Furthermore, it includes the intended usage, re-usage, recycling, and the end-of-life treatment including final disposal. All these impacts can range from slight to significant and are important to investigate.

The use of “life cycle thinking”, meaning consideration for all the environmental impacts of a product at all stages of its life cycle, applied to a product when making medical face masks design decisions can have a significant impact.

Environmental aspects can be documented using a standard template, such as Table 1 of CEN Guide 4:2008. Manufacturers can use such a table to track performance, whilst others can use it to compare products for procurement.

The potential to reduce the environmental impact can be achieved by considerations in your procurement and tender process, for example:

- consider how you can minimize water, energy and detergent use, both during manufacture and when reprocessing the medical devices;
- consider minimizing raw material use during manufacturing;
- consider materials which reduce greenhouse gas emissions and minimize the product's carbon footprint;
- consider the environmental impact of the transport of both the raw materials and the final products, and how to minimize the supply chain to reduce unwanted emissions.

Manufacturers might take into consideration the different requirements, facilities and ability for recycling and recovery for a given geographical area. Manufacturers are encouraged to provide practical advice to purchasers and consumers on how to recycle or recover these resources. Modern supply chain technologies for traceability can be used to evaluate performance across the life cycle of a product.

Documents which are useful to manufacturers when considering the environmental impact of their design and material selection decisions include:

1. The [Waste Framework Directive 2008/98/EC](#), which provides the concept of waste hierarchy, and which ranks the waste management practices from highest to lowest priority as follows: prevention, preparing for reuse, recycling, recovery, and disposal.
2. [CEN Guide 4:2008](#), Guide for addressing environmental issues in product standards adopted by the CEN Technical Board through resolution BT C065/2008.
3. The [ISO 59000](#) series of standards, currently under development by ISO/TC 323 (Circular Economy).
4. [ISO 14001](#), *Environmental management systems — Requirements with guidance for use*
5. An Environmental Product Declaration (EPD) is defined by [International Organization for Standardization](#) (ISO) 14025 as a Type III declaration that “quantifies environmental information on the life cycle of a product to enable comparisons between products fulfilling the same function.” The EPD methodology is based on the Life Cycle Assessment (LCA) tool that follows ISO series 14040.
6. “[A European Strategy for Plastics in a Circular Economy](#)” from the European Commission (2018).
7. [ISO 14006:2020](#), *Environmental management systems — Guidelines for incorporating ecodesign*
8. “[A new Circular Economy Action Plan For a cleaner and more competitive Europe](#)” from the European Commission (2020)



## Annex ZA (informative)

### Relationship between this European Standard and General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European Standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [O] L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative 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 General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex ZA. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

**Table ZA.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up**

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this EN	Remarks / Notes
Chapter 1, Clause 1	5	Only covered in respect to the requirements indicated in the standard
Chapter 2, Clause 11.1 (c)	5.2.5	

**WARNING 1** — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

**WARNING 2** — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

## Bibliography

- [1] EN 149:2001+A1:2009, *Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking*
- [2] EN 1174 (all parts), *Sterilization of medical devices — Estimation of the population of micro-organisms on product*
- [3] EN 14065:2016, *Textiles — Laundry processed textiles — Biocontamination control system*
- [4] EN ISO 139, *Textiles — Standard atmospheres for conditioning and testing (ISO 139)*
- [5] EN ISO 10993 (all parts), *Biological evaluation of medical devices (ISO 10993 (all parts))*
- [6] EN ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)*
- [7] EN ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements (ISO 15223-1:2021)*
- [8] EN ISO 16972:2020, *Respiratory protective devices — Vocabulary and graphical symbols (ISO 16972:2020)*
- [9] EN ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*
- [10] EN ISO 22610:2006, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration (ISO 22610:2006)*
- [11] Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices
- [12] Bagheri S. et al. Size, concentration, and origin of human exhaled particles and their dependence on human factors with implications on infection transmission, 2021, <https://www.pnas.org/doi/10.1073/pnas.2110117118>
- [13] Bagheri T. et al. An upper bound on one-to-one exposure to infectious human respiratory particles, 2021, <https://www.pnas.org/doi/10.1073/pnas.2110117118>
- [14] Tvřzová. Hrubanová, et al., Bacterial filtration efficiency of medical face masks – Evaluation of the use of disposable plastic petri dishes in Andersen impactor, 2022, <https://www.sciencedirect.com/science/article/abs/pii/S0167701222002500>
- [15] Rengasamy S., Shaffer R., Williams B., Smit S. A comparison of facemask and respirator filtration test methods. J. Occup. Environ. Hyg. 2017, 14 (2) pp. 92–103
- [16] ISO 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*