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Medicinske maske za obraz - Zahteve in preskusne metode

Medical face masks - Requirements and test methods

Medizinische Gesichtsmasken - Anforderungen und Prüfverfahren

Masques à usage médical - Exigences et méthodes d'essai

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EUROPEAN STANDARD

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Medical face masks - Requirements and test methods

Masques à usage médical - Exigences et méthodes
d'essaiMedizinische Gesichtsmasken - Anforderungen und
Prüfverfahren

This European Standard was approved by CEN on 19 November 2018 and includes Corrigendum AC approved by CEN on 19 November 2018.

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

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EN 14683:2019+AC:2019 (E)**European foreword**

This document (EN 14683:2019+AC:2019) 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of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.

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 includes Corrigendum 1 issued by CEN on 7 August 2019.

This document supersedes AC EN 14683:2019 AC.

This document includes the corrigendum 1 which updates a requirement in clause B.7.4.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags AC AC.

This document has been prepared under a standardization request 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.

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The main changes compared to the previous edition are:

- a) the appropriate method for *in vitro* determination of bacterial filtration efficiency (BFE) provided in Annex B has been updated;
- b) the former deleted note in 5.2.3 on the breathability requirements has been reintroduced as standard text; it provides a recommendation regarding the use of a respiratory protective device;
- c) the performance requirements on the breathability (differential pressure) provided in Table 1 have been increased and the appropriate method for determination provided in Annex C has been completely reviewed;
- d) the determination of the microbial cleanliness (bioburden) has been slightly updated and moved from 5.2.5 to a new informative Annex D.

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 Macedonia, Romania, Serbia, 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. 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.

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EN 14683:2019+AC:2019 (E)**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 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 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 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)*

EN ISO 11737-1:2018, *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)*

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3 Terms and definitions

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

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

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

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

3.4 cleanliness

freedom from unwanted foreign matter

Note 1 to entry: Such matter can be microorganisms, organic residues or particulate matter.

3.4.1 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”.

3.5 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.

3.6 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.

3.7 filter

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

3.8 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

3.9 medical face 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 may occur via splashes.

3.10 splash resistance

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

3.11 surgical procedure

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

EN 14683:2019+AC:2019 (E)**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. The 'R' signifies splash resistance.

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.

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.

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 masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.

When a 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 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 European Standard. 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.

5.2.5 Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 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 mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D.

The number of masks that shall be tested is minimum 5 of the same batch/lot.

Other test conditions as described in EN ISO 11737-1:2018 may be applied.

In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.

5.2.6 Biocompatibility

According to the definition and classification in EN ISO 10993-1:2009, 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 10993-1:2009 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.

5.2.7 Summary of performance requirements

Table 1 — Performance requirements for medical face masks

Test	Type I ^a	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm ²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	$\geq 16,0$
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 Marking, labelling and packaging

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.

The following information shall be supplied:

- a) number of this European Standard;