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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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Medical face masks - Requirements and test methods

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This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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European foreword

This document (prEN 14683:2023) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 14683:2019+AC:2019.

prEN 14683:2023 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) The 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 regards 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;

i) Annex D “Test procedure for microbial cleanliness” has been completely revised;

j) A new informative Annex E “Rationales” has been added to provide a concise rationale for the important requirements of this document;

k) A new informative Annex F “Transparent medical face masks” has been added;

l) A new informative Annex G “Environmental impact” has been added;

m) Alignment to Regulation (EU) 2017/745 (including updated Annex ZA);

n) 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.

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).

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.

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, *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

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 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.

3.7
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
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.

3.10
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 intended to be used once only for a single individual

3.13
splash resistance
ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure

3.14
surgical procedure
surgical intervention penetrating by skin or mucosa, performed by a surgical team under controlled environmental conditions

3.15
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.

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.

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.

NOTE If raw materials according to ISO 22609:2004 are not available, the formulation for synthetic blood in ASTM F1862 can be used.

5.2.5 Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1:2018 the bioburden of the medical face 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 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