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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

Masques à usage médical - Exigences et méthodes d'essai

Medizinische Gesichtsmasken - Anforderungen und Prüfverfahren

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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of an identical text or by endorsement, at the latest by July 2025, and conflicting national standards shall be withdrawn at the latest by July 2025.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,[1] *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

[1] As impacted by EN ISO 11737-1:2018/A1:2021.

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.