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English Version

Medical face masks - Requirements and test methods

Masques à usage médical - Exigences et méthodes d'essai

Medizinische Gesichtsmasken - Anforderungen und Prüfverfahren

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

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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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.