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Operationsmunskydd – Krav och provningsmetoder

Medical face masks – Requirements and test methods

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Europastandarden EN 14683:2019+AC:2019 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 14683:2019+AC:2019.

Denna standard ersätter SS-EN 14683:2019, utgåva 3.

The European Standard EN 14683:2019+AC:2019 has the status of a Swedish Standard. This document contains the official version of EN 14683:2019+AC:2019.

This standard supersedes the SS-EN 14683:2019, edition 3.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Operationstextilier, SIS/TK 333.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14683:2019+AC

August 2019

ICS 11.140

English Version

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 19 November 2018 and includes Corrigendum AC approved by CEN on 19 November 2018.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 14683:2019+AC:2019 E

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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.

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.

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)*

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