BSI Standards Publication

Medical face masks – Requirements and test methods

bsi.

National foreword

This British Standard is the UK implementation of EN 14683:2019, incorporating corrigendum August 2019. It supersedes BS EN 14683:2014, which is withdrawn.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. Text altered by CEN corrigendum August 2019 is indicated in the text by AC AC.

The UK participation in its preparation was entrusted to Technical Committee CH/205/1, Medical textiles.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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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 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 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of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.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