Surgical masks - Requirements and test methods

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 14683:2005 sisaldab Euroopa standardi EN 14683:2005 ingliskeelset teksti. Käesolev dokument on jõustatud 28.12.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 14683:2005 consists of the English text of the European standard EN 14683:2005. This document is endorsed on 28.12.2005 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This European Standard specifies construction and performance requirements, and test methods for surgical masks intended to limit the transmission of infective agents from staff to patients and (in certain situations vice-versa) during surgical procedures in operating theatres and other medical settings with similar requirements.	**Scope:** This European Standard specifies construction and performance requirements, and test methods for surgical masks intended to limit the transmission of infective agents from staff to patients and (in certain situations vice-versa) during surgical procedures in operating theatres and other medical settings with similar requirements.

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Võtmesõnad: contamination, definition, health protection, hygiene, infection

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Surgical masks - Requirements and test methods

Masques chirurgicaux - Exigences et méthodes d'essai

Chrirurgische Masken - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 19 September 2005.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This European Standard (EN 14683:2005) 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 May 2006, and conflicting national standards shall be withdrawn at the latest by May 2006.

This European Standard has been prepared under a mandate 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 European Standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and 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 e.g. noses and mouths of the surgical team. The main intended use of surgical masks is to protect the patients from infective agents from the noses and mouths of the staff and, in certain situations, additionally to protect the wearer against splashes of potentially contaminated liquids.

1 Scope

This European Standard specifies construction and performance requirements, and test methods for surgical masks intended to limit the transmission of infective agents from staff to patients and (in certain situations vice-versa) during surgical procedures in operating theatres and other medical settings with similar requirements.

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 surgical masks.

2 Normative references

The following referenced documents are indispensable for the application of this European Standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM F1862, *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1
surgical mask
medical device covering the mouth, nose and chin providing a barrier to minimise the direct transmission of infective agents between staff and patient

NOTE Transmission of blood-borne agents from patients to staff may occur via splashes.

3.2
bacterial filtration efficiency (BFE)
effectiveness of a surgical mask in capturing aerosol droplets containing bacteria

3.3
differential pressure
pressure drop across a surgical mask under specific conditions of air flow, temperature and humidity

NOTE The differential pressure is an indicator of the "breathability" of the mask.

3.4
colony forming unit (cfu)
particle containing one or more bacterial cells which gives rise to a single bacterial colony on a culture plate

3.5
infective agent
micro-organism that has been shown to cause surgical wound infections or that might cause infection in the patient or in members of the surgical team