SLOVENSKI STANDARD
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Kirurške maske – Zahteve in preskusne metode

Surgical masks - Requirements and test methods

Chirurgische Masken - Anforderungen und Prüfverfahren

Masques chirurgicaux - Exigences et méthodes d'essai

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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.

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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.

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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of an identical text or by endorsement, at the latest by May 2006, and conflicting national standards shall be withdrawn at the latest by May 2006.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

3.6
surgical procedure
surgical intervention penetrating skin or mucosa, performed by a surgical team under controlled environmental conditions

3.7
aerosol
suspension of solid, liquid, or solid and liquid, particles in a gaseous medium, the particles having a negligible falling velocity (see EN 132)

NOTE This velocity is generally considered to be less than 0,25 m/s.

4 Classification

Surgical masks specified in this European Standard are classified into two types according to bacterial filtration efficiency and differential pressure and each type is further divided according to whether or not the masks are splash resistant.

5 Requirements

5.1 General

5.1.1 Materials and construction

The surgical mask shall not disintegrate, split or tear during intended use.

5.1.2 Design

The surgical mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.

5.2 Performance requirements

5.2.1 Bacterial filtration efficiency (BFE)

When tested in accordance with Annex B, the bacterial filtration efficiency (BFE) of the surgical mask shall conform to the minimum value given for the relevant type in Table 1.

5.2.2 Breathability

When tested in accordance with Annex C, the differential pressure of the surgical mask shall conform to the value given for the relevant type in Table 1.

NOTE 1 If the use of a respiratory protective device as surgical mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant PPE standard(s).

NOTE 2 Differential Pressure is expressed in Pa. 1 Pa equals 9,806 times pressure expressed in mm water.

5.2.3 Splash resistance

When tested in accordance with ASTM F1862, the resistance of the surgical mask to penetration of splashes of liquid shall conform to the minimum value given for the relevant type in Table 1.

Table 1 — Performance requirements for surgical masks

Test	Type I	Type IR	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 95	≥ 98	≥ 98
Differential pressure (Pa)	< 29,4	< 49,0	< 29,4	< 49,0
Splash resistance pressure (mm Hg)	Not required	≥ 120	Not required	≥ 120
NOTE Type IR and Type IIR are splash resistant types.				

6 Testing requirements

All tests shall be carried out on finished products or samples cut from finished products, if appropriate in their sterile state.

Unless otherwise specified for a particular test, samples for testing shall be conditioned at (20 ± 2) °C and (65 ± 2) % relative humidity for the time required to bring them into equilibrium with atmosphere.

7 Labelling and information to be supplied

Annex 1 § 13 of the Medical Devices Directive (93/42/EEC) specifies the information that has to be specified on the packaging in which the surgical mask is supplied.

The following information shall be supplied in addition:

a) number of this European Standard;

b) type of mask (as indicated in Table 1).