

Ühekordselt kasutatavad meditsiinilised kindad. Osa 3: Nõuded ja katsetamine bioloogiliseks hindamiseks

Medical gloves for single use - Part 3: Requirements and testing for biological evaluation

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 455-3:2007 sisaldab Euroopa standardi EN 455-3:2006 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 29.01.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 455-3:2007 consists of the English text of the European standard EN 455-3:2006.</p> <p>This document is endorsed on 29.01.2007 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala: This part of EN 455 specifies requirements for the evaluation of biological safety for medical gloves for single use. It gives requirements for labelling and the disclosure of information relevant to the test methods used.</p>	<p>Scope: This part of EN 455 specifies requirements for the evaluation of biological safety for medical gloves for single use. It gives requirements for labelling and the disclosure of information relevant to the test methods used.</p>
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Võtmesõnad:

English Version

**Medical gloves for single use - Part 3: Requirements and testing
for biological evaluation**

Gants médicaux non réutilisables - Partie 3: Exigences et
essais pour évaluation biologique

Medizinische Handschuhe zum einmaligen Gebrauch - Teil
3: Anforderungen und Prüfung für die biologische
Bewertung

This European Standard was approved by CEN on 13 October 2006.

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.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (EN 455-3:2006) 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 June 2007, and conflicting national standards shall be withdrawn at the latest by June 2007.

This document supersedes EN 455-3:1999.

This document 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 93/42/EEC.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

EN 455 consists of the following parts under the general title "Medical gloves for single use":

- Part 1: Requirements and testing for freedom from holes
- Part 2: Requirements and testing for physical properties
- Part 3: Requirements and testing for biological evaluation

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

Adverse reactions to proteins in latex products have been reported over several years in variable rates of prevalence. Additionally, adverse reactions due to chemicals, lubricants, sterilization residues, pyrogens or other residues are described in the scientific literature. Adverse reactions are most often reported due to gloves made from natural rubber latex, but some of the reactions can also be seen due to gloves made from synthetic polymers.

EN ISO 10993 specifies requirements and test methods for biological evaluation of medical devices. However it does not specifically address adverse reactions that can result from the use of medical gloves (e.g. immediate type allergies). These adverse reactions occur to specific allergens that can be present in gloves. Several factors contribute to the risk of reaction:

- a) the duration and frequency of skin contact with gloves;
- b) the exposure to the allergens through direct contact to mucosa and skin (especially when not intact) and by inhalation of particles;
- c) the occlusive nature of the glove/skin interaction during glove use.

This part of EN 455 gives requirements and test methods for evaluation of the biological safety of medical gloves as part of a risk management process, in accordance with EN ISO 14971 and EN ISO 10993.

1 Scope

This part of EN 455 specifies requirements for the evaluation of biological safety for medical gloves for single use. It gives requirements for labelling and the disclosure of information relevant to the test methods used.

2 Normative references

The following referenced documents are indispensable for the application 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 980, *Graphical symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

EN ISO 10993 (all parts), *Biological evaluation of medical devices*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2000)*

EN ISO 21171:2006, *Medical gloves — Determination of removable surface powder (ISO 21171:2006)*

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