ÜHEKORDSELT KASUTATAVAD MEDITSIINILISED KINDAD. OSA 3: BIOLOOGILISE HINDAMISE NÕUDED JA KATSETAMINE

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

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 455-3:2023 sisaldab Euroopa standardi EN 455-3:2023 ingliskeelset teksti.	This Estonian standard EVS-EN 455-3:2023 consists of the English text of the European standard EN 455-3:2023.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.11.2023.	Date of Availability of the European standard is 29.11.2023.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.140

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 455-3

November 2023

ICS 11.140

Supersedes EN 455-3:2015

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 29 October 2023.

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, Türkiye 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 455-3:2023 E

Contents

Page

European foreword

This document (EN 455-3:2023) 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 2024, and conflicting national standards shall be withdrawn at the latest by November 2025.

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 supersedes EN 455-3:2015.

Compared to the previous edition EN 455-3:2015 the following main changes have been introduced:

a) update of Clause 3 'Terms and definitions';

b) update of Clause 4 'Requirements' especially in regard of the subclauses 'Chemicals', 'Endotoxins' and 'Labelling';

c) clarification of 5.3, NOTE 2

d) update of Clause 6 'Test report'

e) alignment of Annex ZA to the MDR;

f) complete editorial revision.

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;

— Part 4: Requirements and testing for shelf life determination.

The following part is under development:

— Part 5: Extractable chemical residues.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

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

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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 North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the 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 10993.

Users and choosers who are looking for guidance for selection, storage and use of medical gloves for single use are referred to CEN/TR 16953:2017.

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 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 10993-1:2020, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)*

EN ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements (ISO 15223-1:2021)*

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

European Pharmacopoeia, 10th edition, General chapter 2.6.14 Bacterial Endotoxins: publisher EDQM - Council of Europe; 7 allée Kastner, CS 30026, F-67081 Strasbourg; France http://www.edqm.eu/

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:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
endotoxin
lipo-polysaccharide originating from the outer cell-membrane of Gram-negative bacteria

Note 1 to entry: Endotoxins are one type of pyrogen. Sources of endotoxins can include bacterial contamination of the raw materials, especially the process water used during manufacturing and manual handling of the gloves, and can be present on gloves post sterilisation.

3.2
pouch
peel pack
package for aseptic presentation of a single glove or pairs of gloves

3.3
dispenser pack
package, intended for distribution to a consumer, containing loose gloves or peel packs