SLOVENSKI STANDARD
SIST EN 455-3:2024

01-marec-2024

Nadomešča:
SIST EN 455-3:2015

Medicinske rokavice za enkratno uporabo - 3. del: Zahteve in preskušanje za biološko ovrednotenje

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

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

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

Ta slovenski standard je istoveten z: **EN 455-3:2023**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

SIST EN 455-3:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 455-3

November 2023

ICS 11.140

Supersedes EN 455-3:2015

English Version

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This European Standard was approved by CEN on 29 October 2023.

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

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Ref. No. EN 455-3:2023 E

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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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by November 2025.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

3.4
powder
all water insoluble material on the surface of a glove that is removed by washing under the conditions of the test

[SOURCE: EN ISO 21171:2006, 3.1]

Note 1 to entry: This includes both deliberately added powder and other processing aids or materials accidentally present which may be readily detached from the surface of the glove. For the purpose of this document any glove containing 2 mg or less powder is a powder-free glove and more than 2 mg is a powdered glove (for requirement see 4.4).

3.5
process limit
highest value likely to be encountered for a validated manufacturing process

3.6
proteins, allergenic
proteins capable of causing a type I allergic reaction

3.7
proteins, leachable
aqueous proteins and peptides extractable from the final product

3.8
pyrogen
substance creating fever in rabbits which can be related to fever and other adverse reactions in humans

4 Requirements

4.1 General

Medical gloves shall be compliant with EN ISO 10993-1:2020.

4.2 Chemicals

Chemicals which are relevant in accordance with the scope of this document are substances added or formed during any step of the manufacturing process or in storage which may be available in the final product.

These can include lubricants, chemical coatings and sterilizing agents. Several chemical ingredients are commonly used during processing of gloves, some of them are known to cause type IV allergic reactions. The type and amount of residual chemicals added and finally present are variable.

Gloves shall not be dressed with talcum powder (magnesium silicate).

A list of chemical ingredients either added during manufacturing or already known to be present in the product such as accelerators, antioxidants and biocides which are known to cause adverse health effects based on current data shall be made available from the manufacturer.

NOTE An example of ingredients which can cause adverse health effects are Type IV allergens.

The absence of a substance shall only be declared if the substance is not used in any part of the manufacturing process. No compounds shall be used in the manufacture of the product, which are known to form a substance that is subject of such a declaration.

4.3 Endotoxins

If sterile gloves are to be labelled as “low endotoxin gloves”, they shall be tested using the test method specified in 5.1. For such labelled gloves the endotoxin content shall not exceed the limit of 20 endotoxin units per pair of gloves.

NOTE Some healthcare procedures are particularly sensitive to the presence of endotoxin, and therefore it is necessary to minimise endotoxin levels to mitigate the clinical risk. For example, it is important to avoid endotoxin biocontamination during procedures relating to the Central Nervous System [1] and during orthopaedic implantation [2]. For such procedures, users can choose to wash gloves according to protocols that ensure endotoxin removal, or to use a ‘low endotoxin’ glove which complies with the requirements of 4.3.

4.4 Powder-free gloves

For powder-free gloves the total quantity of powder residues determined according to the test method under 5.2 shall not exceed 2 mg per glove. Any glove containing more than 2 mg powder is a powdered glove.

NOTE 1 The use of powder-free gloves is strongly recommended; numerous adverse health effects of glove donning powder have been described in the literature [2-14]. Several countries have banned the use of powdered gloves, including: United States of America [15], Japan [16], Philippines [17], Saudi Arabia [18], Bahrain [19], Thailand, Hong Kong, Taiwan, Korea.

NOTE 2 There is no agreement amongst experts on the maximum amount of powder which can be present on a powdered medical glove, nor the need to specify an upper limit. Sterile medical gloves are required to be washed to remove donning powder before commencing invasive procedures, see 4.6 f).

4.5 Proteins, leachable

The manufacturing process shall aim to minimize the leachable protein level.

The leachable protein content in the finished gloves containing natural rubber latex shall be monitored by the method specified in 5.3 and described in Annex A and it shall be ensured that the process limit is not exceeded. The documentation of these results shall be retained. The results of the test and applied test method shall be made available on request.

NOTE 1 This document specifies a method of measuring a broad approximation for the allergen content, i.e. leachable proteins. Quantitative methods to measure allergenic proteins are described in Annex B.

NOTE 2 It is not possible to specify a safe maximum level of protein because not all proteins are allergenic (allergenicity can depend on the structural orientation of the protein molecule - the so called ‘epitope’). However, the peer reviewed literature supports the view that minimising leachable protein levels mitigates the risk of latex allergy [20].

4.6 Labelling

In addition to the relevant symbols given in EN ISO 15223-1:2021, the following requirements apply:

a) medical gloves shall be labelled for single use on one individual during a single procedure.

NOTE 1 This is in accordance with the Regulation (EU) 2017/745.

For any medical glove the product labelling shall not include any term suggesting disinfection, reprocessing or re-use;