

<b>STN</b>	<b>Zdravotnícke rukavice na jedno použitie Časť 3: Požiadavky a skúšanie na biologické hodnotenie</b>	<b>STN EN 455-3</b>  63 7414
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Medical gloves for single use - Part 3: Requirements and testing for biological evaluation

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/24

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EUROPEAN STANDARD

**EN 455-3**

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## 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.

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**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by November 2025.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

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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.



## EN 455-3:2023 (E)

### 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, 10<sup>th</sup> 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/>

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**