

<b>STN</b>	<b>Lekárske rukavice na jedno použitie Časť 1: Požiadavky a skúšanie na nepremokavosť</b>	<b>STN EN 455-1+A2</b>  63 7414
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Medical gloves for single use - Part 1: Requirements and testing for freedom of holes

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. 02/25

Obsahuje: EN 455-1:2020+A2:2024

Oznámením tejto normy sa ruší  
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EUROPEAN STANDARD

**EN 455-1:2020+A2**

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2024

ICS 11.140

Supersedes EN 455-1:2020+A1:2022

English Version

## Medical gloves for single use - Part 1: Requirements and testing for freedom of holes

Gants médicaux non réutilisables - Partie 1 : Exigences  
et essais pour la détection de l'absence de trous

Medizinische Handschuhe zum einmaligen Gebrauch -  
Teil 1: Anforderungen und Prüfung auf Dichtheit

This European Standard was approved by CEN on 16 December 2021 and includes Amendment 2 approved by CEN on 12 August 2024.

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**

**EN 455-1:2020+A2:2024 (E)**

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## European foreword

This document (EN 455-1:2020+A2:2024) 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 March 2025, and conflicting national standards shall be withdrawn at the latest by March 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  $\boxed{A_2}$  EN 455-1:2020+A1:2022  $\boxed{A_2}$ .

This document includes Amendment 1 approved by CEN on 23 February 2022 and Amendment 2 approved by CEN on 12 August 2024.

The start and finish of text introduced or altered by amendment is indicated in the text by tags  $\boxed{A_1}$   $\boxed{A_1}$  and  $\boxed{A_2}$   $\boxed{A_2}$ .

In comparison with the previous 2000 edition, the following main changes have been introduced to the 2020 edition:

- a) The term 3.1 “medical gloves for single-use” has been amended by a Note to entry;
- b) The term 3.2 “hole” has been added;
- c) In 5.1 the referee testing has been enhanced to cover the issue on extension of the glove when it is filled with water;
- d) In Clause 6 the first paragraph has been slightly changed to accommodate the EU commission rules for referencing ISO standards which are not available as EN standards;
- e) Due to that there is currently no standardization request by the EU commission for this part of EN 455 the harmonization process to provide presumption of conformity to the Medical Device Regulation (MDR) cannot be applied. However, to provide at least guidance on the relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 [OJ L 117] aimed to be covered, an Annex A has been added.

This document has been prepared under a standardisation request addressed to CEN and CENELEC 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.

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.

**EN 455-1:2020+A2:2024 (E)**

The following part is under development:

- Part 5: Extractable chemical residues.

A list of all parts in a series can be found on the CEN website.

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.

## 1 Scope

This document specifies requirements and gives the test method for medical gloves for single use in order to determine freedom from holes.

## 2 Normative references

**A2** 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.

ISO 2859-1:1999,<sup>1</sup> *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection* **A2**

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

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<sup>1</sup> As impacted by ISO 2859-1:1999/Cor 1:2001 and ISO 2859-1:1999/Amd 1:2011.