



# SLOVENSKI STANDARD SIST EN 455-2:2024

01-julij-2024

---

## Medicinske rokavice za enkratno uporabo - 2. del: Zahteve in preskusi za ugotavljanje fizikalnih lastnosti

Medical gloves for single use - Part 2: Requirements and testing for physical properties

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 2: Anforderungen und Prüfung der physikalischen Eigenschaften

Gants médicaux non réutilisables - Partie 2 : Exigences et essais pour propriétés physiques

Ta slovenski standard je istoveten z: **EN 455-2:2024**

[SIST EN 455-2:2024](https://standards.iteh.ai/catalog/standards/sist/7e3dbe54-11d8-4276-93ad-e0d691cd0f35/sist-en-455-2-2024)

<https://standards.iteh.ai/catalog/standards/sist/7e3dbe54-11d8-4276-93ad-e0d691cd0f35/sist-en-455-2-2024>

### ICS:

11.140

Oprema bolnišnic

Hospital equipment

**SIST EN 455-2:2024**

**en,fr,de**



EUROPEAN STANDARD

EN 455-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2024

ICS 11.140

Supersedes EN 455-2:2015

English Version

## Medical gloves for single use - Part 2: Requirements and testing for physical properties

Gants médicaux non réutilisables - Partie 2 : Exigences et essais pour propriétés physiques

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 2: Anforderungen und Prüfung der physikalischen Eigenschaften

This European Standard was approved by CEN on 15 April 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.

# Document Preview

[SIST EN 455-2:2024](https://standards.iteh.ai/catalog/standards/sist/7e3dbe54-11d8-4276-93ad-e0d691cd0f35/sist-en-455-2-2024)

<https://standards.iteh.ai/catalog/standards/sist/7e3dbe54-11d8-4276-93ad-e0d691cd0f35/sist-en-455-2-2024>



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

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

<b>Contents</b>	<b>Page</b>
<b>European foreword</b> .....	<b>3</b>
<b>1 Scope</b> .....	<b>5</b>
<b>2 Normative references</b> .....	<b>5</b>
<b>3 Terms and definitions</b> .....	<b>5</b>
<b>4 Dimensions</b> .....	<b>6</b>
<b>4.1 General</b> .....	<b>6</b>
<b>4.2 Length</b> .....	<b>7</b>
<b>4.3 Width</b> .....	<b>7</b>
<b>5 Strength</b> .....	<b>8</b>
<b>5.1 General</b> .....	<b>8</b>
<b>5.2 Force at break</b> .....	<b>8</b>
<b>5.3 Force at break after challenge testing</b> .....	<b>11</b>
<b>6 Test report</b> .....	<b>11</b>
<b>7 Labelling</b> .....	<b>11</b>
<b>Annex ZA (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered</b> .....	<b>12</b>
<b>Bibliography</b> .....	<b>14</b>

## Document Preview

[SIST EN 455-2:2024](https://standards.iteh.ai)

<https://standards.iteh.ai/catalog/standards/sist/7e3dbe54-11d8-4276-93ad-e0d691cd0f35/sist-en-455-2-2024>

## European foreword

This document (EN 455-2:2024) 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 November 2024, and conflicting national standards shall be withdrawn at the latest by November 2024.

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 455-2:2015.

Compared to the previous edition EN 455-2:2015, the following main changes have been introduced:

- a) normative references have been revised;
- b) subclause 4.2 has been updated with regard to recording the measured length (“median” has been removed);
- c) Clause 5 has been updated;
- d) Clause 6 has been updated;
- e) Annex ZA has been updated for harmonization under Medical Device Regulation (EU) 2017/745 (MDR).

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.

The EN 455 series 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.*

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.

**EN 455-2:2024 (E)**

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.

**iTeh Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

[SIST EN 455-2:2024](https://standards.iteh.ai/catalog/standards/sist/7e3dbe54-11d8-4276-93ad-e0d691cd0f35/sist-en-455-2-2024)

<https://standards.iteh.ai/catalog/standards/sist/7e3dbe54-11d8-4276-93ad-e0d691cd0f35/sist-en-455-2-2024>