

# ILNAS

Institut luxembourgeois de la normalisation  
de l'accréditation, de la sécurité et qualité  
des produits et services

## ILNAS-EN 455-2:2024

### **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

05/2024



## National Foreword

This European Standard EN 455-2:2024 was adopted as Luxembourgish Standard ILNAS-EN 455-2:2024.

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EUROPEAN STANDARD <sup>ILNAS-EN 455-2:2024</sup> **EN 455-2**  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

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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.



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>		Page
<b>European foreword</b> .....		<b>3</b>
<b>1</b>	<b>Scope</b> .....	<b>5</b>
<b>2</b>	<b>Normative references</b> .....	<b>5</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>5</b>
<b>4</b>	<b>Dimensions</b> .....	<b>6</b>
<b>4.1</b>	<b>General</b> .....	<b>6</b>
<b>4.2</b>	<b>Length</b> .....	<b>7</b>
<b>4.3</b>	<b>Width</b> .....	<b>7</b>
<b>5</b>	<b>Strength</b> .....	<b>8</b>
<b>5.1</b>	<b>General</b> .....	<b>8</b>
<b>5.2</b>	<b>Force at break</b> .....	<b>8</b>
<b>5.3</b>	<b>Force at break after challenge testing</b> .....	<b>11</b>
<b>6</b>	<b>Test report</b> .....	<b>11</b>
<b>7</b>	<b>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>

## 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.

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 test methods for physical properties of single-use medical gloves (i.e. surgical gloves and examination/procedure gloves) in order to ensure that they provide and maintain in use an adequate level of protection from cross contamination for both patient and user.

This document does not specify the size of a lot. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.

## 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 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 20417:2021, *Medical devices — Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

ISO 23529:2016, *Rubber — General procedures for preparing and conditioning test pieces for physical test methods*

ISO 188:2023, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology 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

#### **medical gloves for single use**

gloves intended for use in the medical field to protect patient and user from cross-contamination

### 3.2

#### **surgical gloves**

sterile, anatomically shaped medical gloves with the thumb positioned towards the palmar surface of the index finger rather than lying flat, and intended for use in invasive surgery

### 3.3

#### **examination gloves procedure gloves**

sterile or non-sterile medical gloves, which can be anatomically shaped, intended for conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical material

3.4

lot

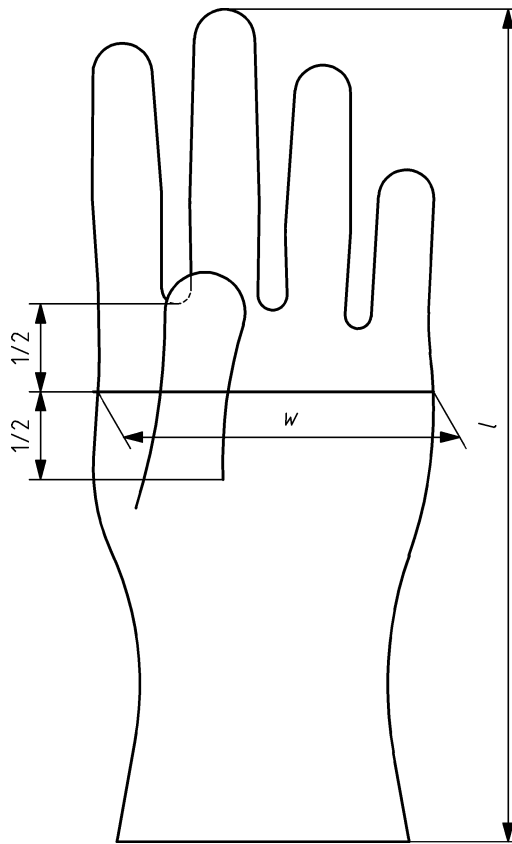
collection of gloves of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed in the same type of individual container

[SOURCE: EN 455-4:2009, 3.4]

4 Dimensions

4.1 General

When measured as described in 4.2 and 4.3 taking 13 samples from each lot, the median value obtained for the dimensions shall be as given in Table 1 and Table 2.



Key

w width

l length

Figure 1 — Designation of length and width of gloves