SLOVENSKI STANDARD
SIST EN 455-2:2015

01-julij-2015

Nadomešča:
SIST EN 455-2:2010+A2:2013

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: Propriétés physiques: exigences et essais

Ta slovenski standard je istoveten z: EN 455-2:2015

ICS:

11.140	Oprema bolnišnic	Hospital equipment

SIST EN 455-2:2015 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 455-2

April 2015

ICS 11.140

Supersedes EN 455-2:2009+A2:2013

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 24 January 2015.

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

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Foreword

This document (EN 455-2:2015) 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of an identical text or by endorsement, at the latest by October 2015 and conflicting national standards shall be withdrawn at the latest by October 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 455-2:2009+A2:2013.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA which is an integral part of this document.

With respect to EN 455-2:2009+A2:2013 the following changes are:

a) normative references revised;

b) new Clause 7 "labelling" introduced;

c) exception for nitrile in Table 3 for median values of force of break deleted;

d) Annex ZA updated.

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*

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

1 Scope

This European Standard 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 European Standard 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 455-4:2009, *Medical gloves for single use — Part 4: Requirements and testing for shelf life determination*

EN 1041:2008+A1:2013, *Information supplied by the manufacturer of medical devices*

EN ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements (ISO 15223-1:2012)*

ISO 188:2007, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

ISO 23529:2010, *Rubber — General procedures for preparing and conditioning test pieces for physical test methods*

3 Terms and definitions

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

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 may or may not be anatomically shaped, intended for conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical material

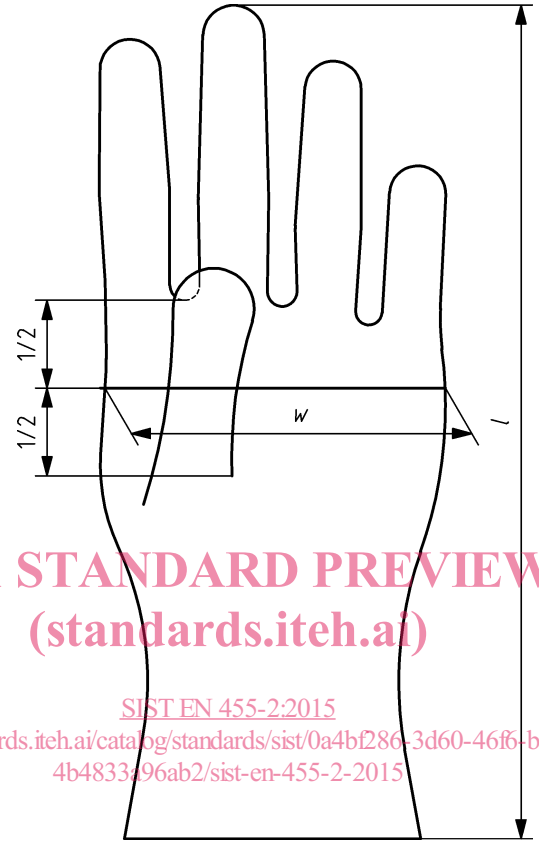
3.4
lot
collection of gloves of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed in the same type of individual container

[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 Tables 1 and 2.



Key

w	width
l	length

Figure 1 — Designation of length and width of gloves

4.2 Length

Measure the length (dimension *l*, as designated in Figure 1) by freely suspending the glove with the middle finger on a vertical graduated rule having a rounded tip so as to fit the shape of the finger tip of the glove. Remove wrinkles and folds without stretching the glove. Record the median measured length.

For greater ease of measurement, the ruler may be angled backwards slightly so that the glove is in contact with the ruler.

4.3 Width

Measure the width (dimension *w*, as designated in Figure 1), to the nearest mm, using a ruler, with the glove placed on a flat surface. Do not stretch the glove.

Table 1 — Dimensions of surgical gloves

Size	Median length[a] l in mm	Median width[b c] w in mm
5	≥ 250	67 ± 4
5,5	≥ 250	72 ± 4
6	≥ 260	77 ± 5
6,5	≥ 260	83 ± 5
7	≥ 270	89 ± 5
7,5	≥ 270	95 ± 5
8	≥ 270	102 ± 6
8,5	≥ 280	108 ± 6
9	≥ 280	114 ± 6
9,5	≥ 280	121 ± 6

a Dimension l as designated in Figure 1.

b Dimension w as designated in Figure 1.

c The width requirements are for gloves made from natural rubber latex and all other elastomeric materials. These dimensions may not be appropriate for gloves made from other materials.

Table 2 — Dimensions of examination/procedure gloves

Size	Median length[a] l in mm	Median width[b c] w in mm
Extra Small	≥ 240	≤ 80
Small		80 ± 10
Medium		95 ± 10
Large		110 ± 10
Extra Large		≥ 110

NOTE Manufacturers may optionally use the sizes and dimensions given in Table 1 in order to provide a wider range of glove sizes.

a Dimension l as designated in Figure 1.

b Dimension w as designated in Figure 1.

c The width requirements are for gloves made from natural rubber latex and all other elastomeric materials. These dimensions may not be appropriate for gloves made from other materials.

5 Strength

5.1 General

Different glove materials require different force at break requirements to ensure an acceptable performance. Absolute force at break values do not directly correlate with the in use performance. Selection of appropriate glove materials for the intended application shall be part of the risk management process.

When the strength of the glove is tested as described in 5.2 at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 5) % r.h. the force at break of gloves shall be as given in Table 3.

5.2 Force at break

5.2.1 Ageing and shelf life requirements are described in EN 455-4:2009.

5.2.2 Obtain one dumb-bell test piece from each of 13 gloves taken from a single lot (from seven pairs of gloves where applicable) using a cutter as specified in Figure 2 from the palm, back of the hand or cuff areas of each glove in the test sample, avoiding textured areas if possible and taking the test pieces in the direction of the longitudinal axis of the glove.