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Część 2: Wymagania i badania dotyczące właściwości fizycznych

Norma Europejska EN 455-2:2015 *Medical gloves for single use – Part 2: Requirements and testing for physical properties* ma status Polskiej Normy

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Niniejsza norma została zatwierdzona przez Prezesa PKN dnia 7 lipca 2015 r.

Komitetem krajowym odpowiedzialnym za normę jest KT nr 247 ds. Materiałów Medycznych i Biomateriałów.

Istnieje możliwość przetłumaczenia normy na język polski na wniosek zainteresowanych środowisk. Decyzję podejmuje właściwy Komitet Techniczny.

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Nota uznaniowa

Norma Europejska EN 455-2:2015 została uznana przez PKN za Polską Normę PN-EN 455-2:2015-07.

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.

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.

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EN 455-2:2015 (E)

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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of an identical text or by endorsement, at the latest by October 2015 and conflicting national standards shall be withdrawn at the latest by October 2015.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.

EN 455-2:2015 (E)

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

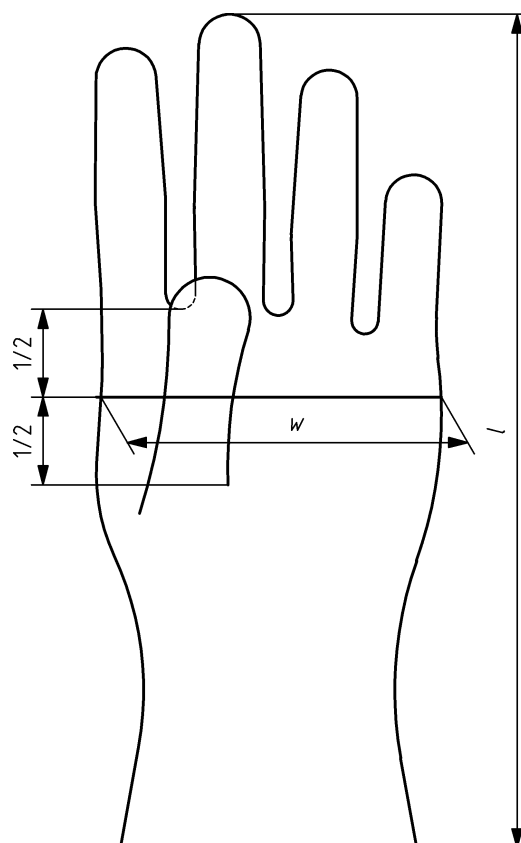
collection of gloves of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed in the same type of individual container

[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.

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Table 1 — Dimensions of surgical gloves

Size	Median length ^a <i>l</i> in mm	Median width ^{b c} <i>w</i> 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 <i>l</i> as designated in Figure 1. ^b Dimension <i>w</i> 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 <i>l</i> in mm	Median width ^{b c} <i>w</i> 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 <i>l</i> as designated in Figure 1.		
^b Dimension <i>w</i> 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 $(23 \pm 2) ^\circ\text{C}$ and a relative humidity of $(50 \pm 5) \% \text{ r.h.}$ the force at break of gloves shall be as given in Table 3.

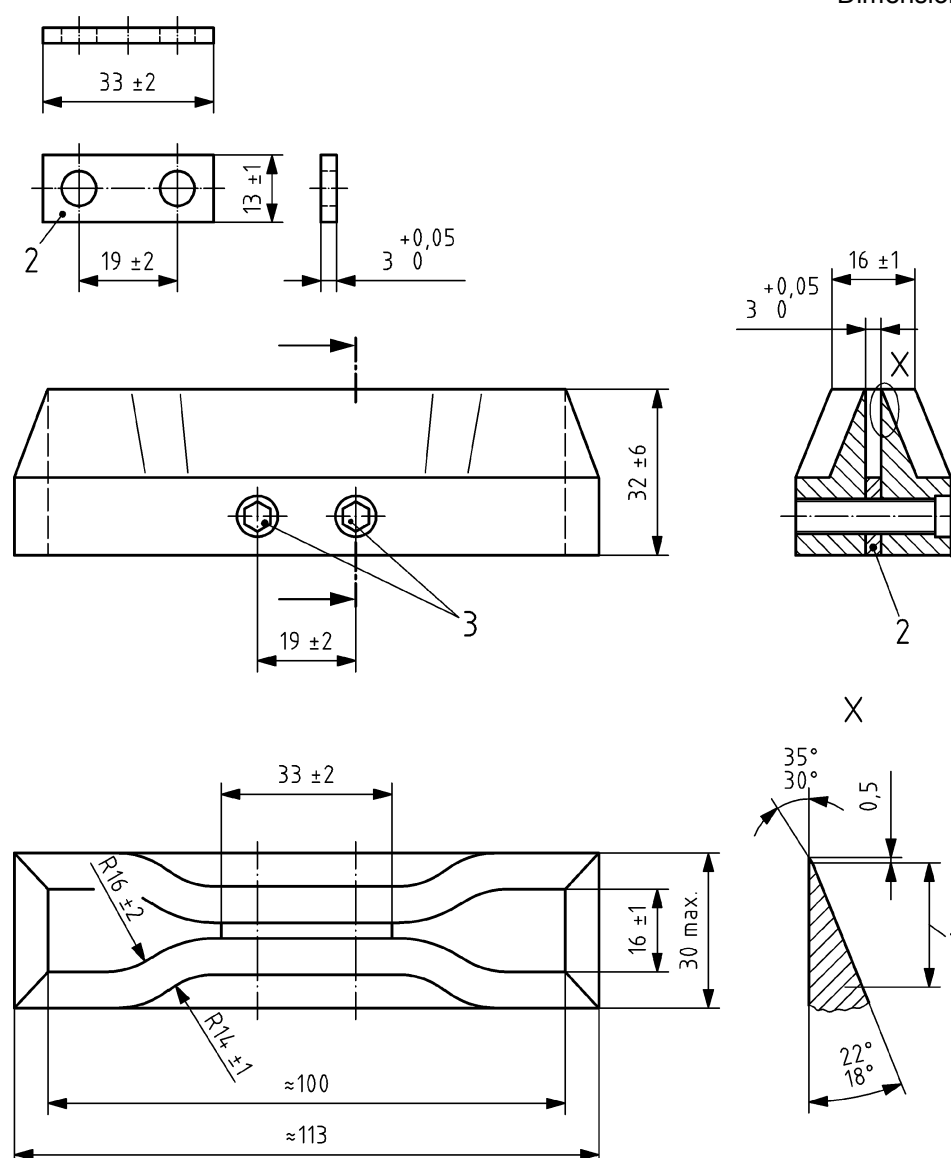
5.2 Force at break

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.

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Dimensions in millimetres



Key

- 1 grind 6 mm/min.
- 2 spacer
- 3 bolts

Figure 2 — Cutter for dumb bell specimens

5.2.3 Determine the force at break of the 13 test pieces after conditioning for a minimum of 16 h. The tensometer should be equipped with a load cell appropriate for the strength of the sample under test, with jaws that firmly grip but do not damage the test specimen and with a crosshead speed of 500 mm/min.

If a test piece breaks at the shoulder, it is not necessary to repeat the test on another test piece.

5.2.4 a) Determine the single wall thickness (t_f) of the same glove as in 5.2.2 at a point on the middle finger within (13 ± 3) mm of the fingertip by measuring the double wall thickness as described in method A of ISO 23529:2010, Clause 7.1, using a gauge with a foot pressure of (22 ± 5) kPa. Take the single wall thickness as one half of the measured double wall thickness.

- b) Measure the thickness of the dumb-bell test pieces (t_X) as described in method A of ISO 23529:2010, Clause 7.1, using the gauge described in 5.2.4 a).
- c) Compare the values of t_f and t_X . If $t_f/t_X \geq 0,9$, no correction to the measured force at break is necessary. If $t_f/t_X < 0,9$, correct the measured value by multiplying the measured force at break (see 5.2.3) by a factor of t_f/t_X .

Although there is no requirement for thickness in this standard, it is recognised that the fingers of a glove may, because of design or manufacturing processes, be significantly thinner and therefore weaker in terms of force to break than at the points from which the test pieces were taken. It is important to ensure that the minimum force at break requirements given in Table 3 is maintained at the fingertips. If the difference in thickness between the fingertip and the point from which the test pieces were taken is small (less than 10 %), no correction is necessary. If this difference is greater than 10 %, a correction factor based on the relative thickness is applied to the measured force at break to obtain a true estimate of the strength of the glove at the fingertip.

5.2.5 Record the force at break, in N, for each of the 13 samples, corrected as described in 5.2.4 if necessary. The median of the recorded results shall comply with the values of Table 3.

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b) c)	
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	$\geq 9,0$	$\geq 6,0$	$\geq 3,6$
a) Requirements for all surgical gloves. b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).. c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			

5.3 Force at break after challenge testing

5.3.1 Gloves packaged in unit packages or gloves taken from bulk packages shall be placed for a period of seven days at a temperature of $(70 \pm 2) ^\circ\text{C}$ in an oven as specified in ISO 188:2007, clause 4.

5.3.2 Measure the force at break as described in 5.2.

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6 Test report

Any test report shall include at least the following information:

- a) reference to this part of EN 455;
- b) the type of glove and the manufacturing batch code;
- c) the name and address of the manufacturer or distributor and test laboratory, if different;
- d) the date of testing performed;
- e) the test results.

7 Labelling

In addition to labelling requirements defined in other parts of EN 455 manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC concerning medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC concerning medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC concerning medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	3, 4	
5	3, 4	

For devices intended by the manufacturer to be for dual use in accordance with Article 1(6) of Directive 93/42/EEC the following Table ZA.2 details the relevant essential requirements of Directive 89/686/EC on Personal Protective Equipment and their corresponding clauses of this European Standard. Table ZA.2 however, does not imply any citation in the OJEU under the PPE directive and thus does not provide presumption of conformity for the PPE directive.

Table ZA.2 — Relevant Essential Requirements from Directive 89/686/EEC on Personal Protective Equipment that are addressed by this European Standard

(according to Article 1 (6) of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 89/686/EEC	Qualifying remarks/Notes
4	1.1.1.	
5	1.3.2.	
7	2.4.	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.