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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

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11.140	Oprema bolnišnic	Hospital equipment

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EUROPEAN STANDARD

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

Gants médicaux non réutilisables - Partie 2 : Propriétés physiques: exigences et essais

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (EN 455-2:2009) 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of an identical text or by endorsement, at the latest by May 2010, and conflicting national standards shall be withdrawn at the latest by May 2010.

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 455-2:2000.

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.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland 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 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 referenced documents are indispensable for the application 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 188, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat resistance tests*

ISO 23529:2004, *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 laying 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

[EN 455-4:2009]

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.

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.

NOTE 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] in mm	Median width[b c] 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] in mm	Median width [b c] 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.

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.

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.

NOTE 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 finger tip by measuring the double wall thickness as described in method A of ISO 23529:2004, 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 23529:2004, 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.

NOTE 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 are 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 N				
	Surgical gloves		Examination/procedure gloves		
	a)	b)	c)	d)	e)
During shelf life	≥ 12,0	≥ 9,0	≥ 9,0	≥ 6,0	≥ 3,6
After challenge testing according to 5.3	≥ 9,0	≥ 6,0	≥ 6,0	≥ 6,0	≥ 3,6

a) Requirements for gloves made from natural rubber latex.

b) Requirements for gloves made from all other elastomeric materials, e.g. polychloroprene, synthetic polyisoprene, nitrile, styrene block copolymers, polyurethane.

c) Requirements for gloves made from elastomeric materials except nitrile, e.g. natural rubber latex, polychloroprene, synthetic polyisoprene, styrene block copolymers, polyurethane.

d) Requirements for gloves made from nitrile.

e) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).

5.3 Force at break after challenge testing

5.3.1 Place gloves packaged in unit packages or gloves taken from bulk packages for a period of seven days at a temperature of (70 ± 2) °C in an oven as specified in ISO 188.