SLOVENSKI STANDARD
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Medicinske rokavice za enkratno uporabo - 2. del: Zahteve in preskusi za ugotavljanje fizikalnih lastnosti (vkljuļ no s tehniļ nim popravkom 1:1996)

Medical gloves for single use - Part 2: Requirements and testing for physical properties (including Technical Corrigendum 1:1996)

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 2: Anforderungen und Prüfung der physikalischen Eigenschaften (einschließlich Technische Korrektur 1:1996)

Gants médicaux non réutilisables - Partie 2: Propriétés physiques: exigences et essais (Rectificatif Technique 1:1996 inclus)

Ta slovenski standard je istoveten z: **EN 455-2:2000**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

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EUROPEAN STANDARD
NORME EUROPÉENNE
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EN 455-2

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Supersedes EN 455-2:1995

English version

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This European Standard was approved by CEN on 16 September 2000.

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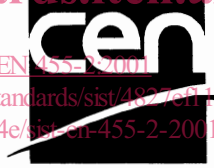
This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard supersedes EN 455-2:1995

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 April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.

This European Standard 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 standard.

This European Standard applies to medical gloves for single use and has been prepared in three parts. This part addresses physical properties ; Part 1 addresses freedom from holes and Part 3 addresses requirements and testing for biological evaluation.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This Part of this 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.

2 Normative References

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

ISO 188
Rubber, vulcanized or thermoplastic - Accelerated ageing and heat resistance tests

ISO 4648
Rubber, vulcanized or thermoplastic – Determination of dimensions of test pieces and products for test purposes

3 Terms and definitions

For the purposes of this standard 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/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
long-cuff medical gloves
a) surgical gloves having a minimum overall length of 300 mm.

b) examination/procedure gloves having a minimum overall length of 270 mm.

3.5
seamed medical gloves; welded gloves
medical gloves manufactured by welding or otherwise bonding together flat films of material.

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 minimum measured length.

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

4.3 Width

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

Table 1 - Dimensions of surgical gloves

Size	Minimum length[1)] mm	Width[2),3)] 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

1) Dimension *l* as designated in figure 1.

2) Dimension *w* as designated in figure 1.

3) The width requirements are for gloves made from natural rubber latex, synthetic rubber latex or solutions of natural and/or synthetic rubber. These dimensions may not be appropriate for gloves made from other materials.

Table 2 - Dimensions of examination/procedure gloves

Size	Minimum length [1] mm		Width[2),3)] mm
	Seamed gloves	Unseamed gloves	
Extra Small	270	240	≤ 80
Small	270	240	80 ± 10
Medium	270	240	95 ± 10
Large	270	240	110 ± 10
Extra Large	270	240	≥ 110

1) Dimension *l* as designated in figure 1

2) Dimension *w* as designated in figure 1

3) The width requirements are for gloves made from natural rubber latex, synthetic rubber latex or solutions of natural and/or synthetic rubber. These dimensions may not be appropriate for gloves made from other materials

5 Strength

5.1 General

When the strength of the glove is tested as described in 5.2, 5.3 and, if appropriate, 5.4 at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 5) % r.h. the force at break of seamed and unseamed gloves shall be as given in Table 3.

5.2 Force at break before accelerated ageing

5.2.1 Obtain one dumb-bell test piece from each of 13 gloves (from 7 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.

5.2.2 Determine the force at break of the 13 test pieces after conditioning for a minimum of 16 hours under ambient conditions of (23 ± 2)°C and a relative humidity of (50 ± 5)% and cross head 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.

5.2.3

a) Determine the single wall thickness (t_f) of the same glove as in 5.2.1 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 A1 of ISO 4648, 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 A1 of ISO 4648, using the gauge described in 5.2.3 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 5.2.2) 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.

5.2.4 Record the force at break, in Newtons, for each of the 13 samples, corrected as described in 5.2.3 if necessary. The median of the recorded results shall comply with the values of table 3.

5.3 Force at break after accelerated ageing

5.3.1 Place gloves packaged in unit packages or gloves taken from bulk packages for a period of 7 days at a temperature of (70 ± 2)°C in an oven as specified in ISO 188.

5.3.2 Measure the force at break as described in 5.2.

5.4 Seamed gloves

5.4.1 Obtain one dumb-bell test piece using a cutter as specified in figure 2 from each of 13 gloves in the test sample such that the seam is present within the length of the narrow parallel portion of the test piece and is at right angles to the long axis of the test piece.

5.4.2 Determine the force at break of the 13 test pieces as described in 5.2.2.

5.4.3 Record the median force at break, in Newtons, of the 13 obtained samples.

5.4.4 Repeat 5.4.1 to 5.4.3 on gloves that have been aged as described in 5.3.1.

Table 3 - The median values of force at break

	Surgical gloves Newtons		Examination/ procedure gloves Newtons	
	a)	b)	c)	d)
Before accelerated ageing	≥ 12	≥ 9	≥ 9	≥ 3,6
After accelerated ageing	≥ 9	≥ 6	≥ 6	≥ 3,6
Seam of seamed gloves before accelerated ageing	≥ 12	≥ 9	≥ 9	≥ 3,6
Seam of seamed gloves after accelerated ageing	≥ 9	≥ 6	≥ 6	≥ 3,6

a) Requirements for gloves made from natural rubber latex.

b) Requirements for gloves made from synthetic rubber latex or solutions of natural or synthetic rubber.

c) Requirements for gloves made from natural rubber latex, synthetic rubber latex or solutions of natural and/or synthetic rubber.

d) Requirements for gloves made from other materials.

6 Test Report

Any test report shall include at least the following information:

- reference to this part of EN 455;
- the type of glove and the manufacturing batch code;

- the name and address of the manufacturer or distributor and test laboratory, if different;
- the date of testing performed;
- the test results.