SLOVENSKI STANDARD
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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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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

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (prEN 455-2:2008) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede 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 EC Directive(s).

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

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

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 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 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/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
a 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[1])

(see pr EN 455-4:2007)

[1]) 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.

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[a] in mm	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, 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 [a] in mm	Width [b c] in mm
Extra Small	240	≤ 80
Small		80 ± 10
Medium		95 ± 10
Large		110 ± 10
Extra Large		≥ 110

[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, 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 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 pr EN 455-4.

5.2.2 Obtain one dumb-bell test piece from each of 13 gloves taken from a single lot (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.

5.2.3 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.

5.2.4

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 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 5.2.4 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 Newton, 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 — The median values of force at break

		Force at break during shelf life in Newton
Surgical gloves	**a)**	≥ 9
	b)	≥ 6
Examination/ procedure gloves	**c)**	≥ 6
	d)	≥ 3,6

a) Requirements for gloves made from natural rubber latex.

b) Requirements for gloves made from all other elastomeric material, e.g. polychloroprene, synthetic polyisoprene, polynitrile, blockpolymers, polyurethane.

c) Requirements for gloves made from natural rubber latex and all other elastomeric material, e.g. see b), including blend of these materials.

d) Requirements for gloves made from thermoplastic material (plasticized polyvinylchloride, polyethylene).

Note 1: It is recognized, that force at break for un-aged gloves results in plus 3 Newton or more higher values.

Note 2:The use of gloves under d) should be limited to certain low risk-based medical applications (type and duration) because of its lower physical performance.

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.

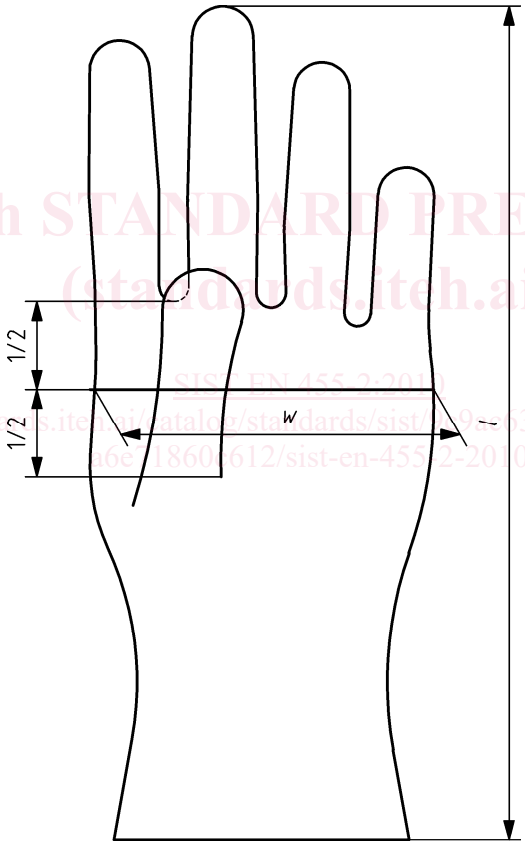

Figure 1 — Designation of length and width of gloves