

ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 455-2:2009+A2:2013



National Foreword

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ILNAS-EN 455-2:2009+A2:2013
EUROPEAN STANDARD **EN 455-2:2009+A2**
NORME EUROPÉENNE
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English Version

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

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

Medizinische Handschuhe zum einmaligen Gebrauch - Teil
2: Anforderungen und Prüfung der physikalischen
Eigenschaften

This European Standard was approved by CEN on 3 October 2009 and includes Amendment 1 approved by CEN on 3 January 2011 and Amendment 2 approved by CEN on 8 January 2013.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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Contents		Page
Foreword		3
1 Scope		4
2 Normative references		4
3 Terms and definitions		4
4 Dimensions		5
4.1 General		5
4.2 Length		5
4.3 Width		5
5 Strength		6
5.1 General		6
5.2 Force at break		6
5.3 Force at break after challenge testing		8
6 Test report		8
Annex ZA (informative) \square_{A2} Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC concerning Medical Devices \square_{A2}		11

Foreword

This document (EN 455-2:2009+A2:2013) 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of an identical text or by endorsement, at the latest by August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

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 $\boxed{A_2}$ EN 455-2:2009+A1:2011 $\boxed{A_2}$.

This document includes Amendment 1, approved by CEN on 2011-01-03 and Amendment 2, approved by CEN on 2013-01-08.

The start and finish of text introduced or altered by amendment is indicated in the text by tags $\boxed{A_1}$ $\boxed{A_1}$ and $\boxed{A_2}$ $\boxed{A_2}$.

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, 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 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.