

STN	Zdravotnícke rukavice na jedno použitie. Časť 2: Požiadavky a skúšanie fyzikálnych vlastností.	STN EN 455-2 63 7414
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Medical gloves for single use - Part 2: Requirements and testing for physical properties

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/15

Obsahuje: EN 455-2:2015

Oznámením tejto normy sa ruší
STN EN 455-2+A2 (63 7414) z júla 2013

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

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of an identical text or by endorsement, at the latest by October 2015 and conflicting national standards shall be withdrawn at the latest by October 2015.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

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN