ÜHEKORDSELT KASUTATAVAD MEDITSIINILISED KINDAD. OSA 2: NÕUDED FÜÜSIKALISTELE OMADUSTELE JA KATSETAMINE

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 455-2:2015 sisaldab Euroopa standardi EN 455-2:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 455-2:2015 consists of the English text of the European standard EN 455-2:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.04.2015.	Date of Availability of the European standard is 29.04.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

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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.

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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

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*

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 lying 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

[SOURCE: EN 455-4:2009, 3.4]