SLOVENSKI STANDARD
oSIST prEN 455-1:2019

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Medicinske rokavice za enkratno uporabo - 1. del: Zahteve in preskusi za ugotavljanje odsotnosti lukenj

Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

Medizinische Handschuhe zum einmaligen Gebrauch - Anforderungen und Prüfung auf Dichtheit

Gants médicaux non réutilisables - Partie1 : Exigences et essais pour la détection de l'absence de trous

Ta slovenski standard je istoveten z: **prEN 455-1**

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11.140	Oprema bolnišnic	Hospital equipment

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EUROPEAN STANDARD

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English Version

Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

Gants médicaux non réutilisables - Partie 1: Détection des trous - Prescriptions et essais

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 1: Anforderungen und PrÃ1/4fung auf Dichtheit

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
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 455-1:2019) 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 455-1:2000.

This document has been prepared under a standardization request 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.

Compared to the previous edition the following main changes have been introduced:

a) The term 3.1 “medical gloves for single-use” has been amended by a Note;

b) The term 3.2 “hole” has been added;

c) In 5.1 the referee testing has been enhanced to cover the issue on extension of the glove when it is filled with water;

d) In Clause 6 the first paragraph has been slightly changed to accommodate the EC rules for referencing ISO standards which are not available as EN standards;

e) The Annex ZA has been updated in alignment to the Medical Device Regulation (MDR).

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.

1 Scope

This document specifies requirements and gives the test method for medical gloves for single use in order to determine freedom from holes.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
medical gloves for single use
gloves intended for use in the medical field to protect patient and user from cross-contamination, intended to be used on one individual during a single procedure

Note 1 to entry: Medical gloves labelled as single use are medical devices for single use according to the Medical Device Regulation (MDR). A single use medical device means a device that is intended to be used on one individual during a single procedure.

3.2
hole
defect of the glove which allows leakage of water

4 Requirement

Medical gloves for single use shall not leak when tested in accordance with Clause 5.

5 Water tightness test for detection of holes

5.1 Referee testing

Vertically position a filling tube of suitable dimensions to fit the glove such that the tube and the glove is capable of holding 1 000 ml of water. If, due to extension of the glove, the 1000 ml does not completely fill the glove, a means of ensuring that all parts of the glove are tested shall be devised. Any modified process should not influence the viability of detection of holes.

NOTE 1 For example, the glove could be clamped to restrict the flow of water sequentially until all parts of the glove have been tested for the required time interval.

NOTE 2 Suggested dimensions of the filling tube are shown in Figure 1.

Attach the glove to the filling tube, overlapping the cuff by a maximum of 40 mm over the end of the tube and secure it by suitable means to obtain a watertight seal without damaging the glove (see Figure 1).