SLOVENSKI STANDARD
oSIST prEN 455-1:2019

01-september-2019

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**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

oSIST prEN 455-1:2019 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 455-1

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ICS 11.140

Will supersede EN 455-1:2000

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.

This draft European Standard was established by CEN 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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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).

Add (1 000 ± 50) ml of water at a temperature of (15 to 35) °C into the open end of the filling tube, allowing the water to pass freely into the glove to ensure an equal distribution into each finger. Some of the water may remain in the filling tube depending on the glove being tested.

Immediately inspect the glove visually for water leakage. Repeat the inspection after a period of 2 min to 3 min. Leakages within 40 mm of the cuff are not relevant.

5.2 Routine testing

Routine testing shall be either by the water tightness test given in 5.1 or by another test which is validated against this test.

6 Sampling, inspection level and AQL

Each lot shall be sampled statistically in accordance with standardized AQL tables for single sampling plans using general inspection level 1, but utilizing a minimum sample size and corresponding acceptance/rejection numbers equivalent to sample size code letter L. When tested by the method described in 5.1 for referee purpose, the compliance level for freedom from holes shall be an AQL of 0,65 for surgical gloves and 1,5 for examination gloves.

NOTE 1 Examples of standardized AQL tables can be found in ISO 2859-1 and ANSI/ASQ Z1.4.

NOTE 2 This inspection level meets the requirements of Annex IV point 6.3 of the Medical Devices Directive, 93/42/EEC, and does not entail excessive sample sizes which would impact on manufacturing and testing costs. A minimum sample size equivalent to sample size code letter L ensures that an adequate assessment of the quality of the lot is obtained when the lot size is small or unknown.

7 Test report

Any test report shall include at least the following information:

— a reference to this part of EN 455;

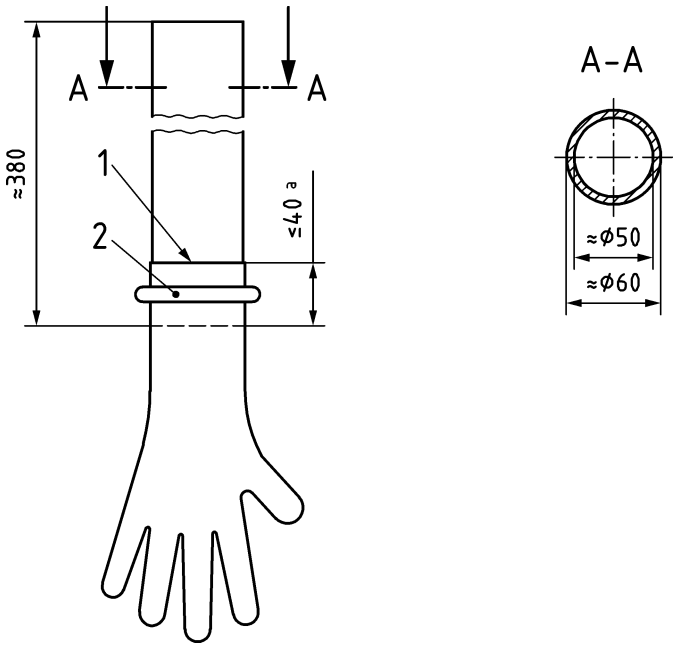
— the type of gloves and manufacturing batch code;

— the name and address of the manufacturer or distributor and test laboratory, if different;

— the date of the test performed;

— the test results (batch size, sample size, number of non-conforming gloves).

Dimensions in milimeters



Key

1 Cuff end of glove
2 Locking device
[a] Fill tube overlapping

Figure 1 — Water tightness test - Filling tube

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 [OJ L 117] aimed to be covered

This European standard has been prepared under a Commission's standardization request [Full reference to the request "M/xxx"] to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s)/subclause(s) of this EN	Remarks/Notes
1	Clause 4, Clause 6	n.a.
2	Clause 4, Clause 6	n.a.
4 (a)	Clause 4, Clause 6	n.a.
8	Clause 4, Clause 6	n.a.
9	Clause 4, Clause 6	n.a.
14.2 (c)	Clause 4, Clause 6	n.a.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Bibliography

[1] ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

[2] ANSI/ASQ Z1.4, *Sampling procedures and tables for inspection by attributes*