BS EN 455-1:2020

BSI Standards Publication

Medical gloves for single use

Part 1: Requirements and testing for freedom from holes

bsi.

National foreword

This British Standard is the UK implementation of EN 455-1:2020. It supersedes BS EN 455-1:2000, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/205/3, Medical gloves.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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NORME EUROPÉENNE

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EN 455-1

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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: Exigences et essais pour la détection de l'absence de trous

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 1: Anforderungen und Prüfung auf Dichtheit

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European foreword

This document (EN 455-1:2020) 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of an identical text or by endorsement, at the latest by November 2020, and conflicting national standards shall be withdrawn at the latest by November 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 455-1:2000.

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 to entry;

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 EU commission rules for referencing ISO standards which are not available as EN standards;

e) Due to that there is currently no standardization request by the EU commission for this part of EN 455 the harmonization process to provide presumption of conformity to the Medical Device Regulation (MDR) cannot be applied. However, to provide at least guidance on the relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 [OJ L 117] aimed to be covered, an Annex A has been added.

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.

The following part is under development:

— Part 5: Extractable chemical residues.

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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 https://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 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 and implemented. Any modified process should not influence the viability of detection of holes.

NOTE 1 For example, the glove can 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 (acceptance quality level) tables for single sampling plans using general inspection level I, 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 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 document (EN 455-1);

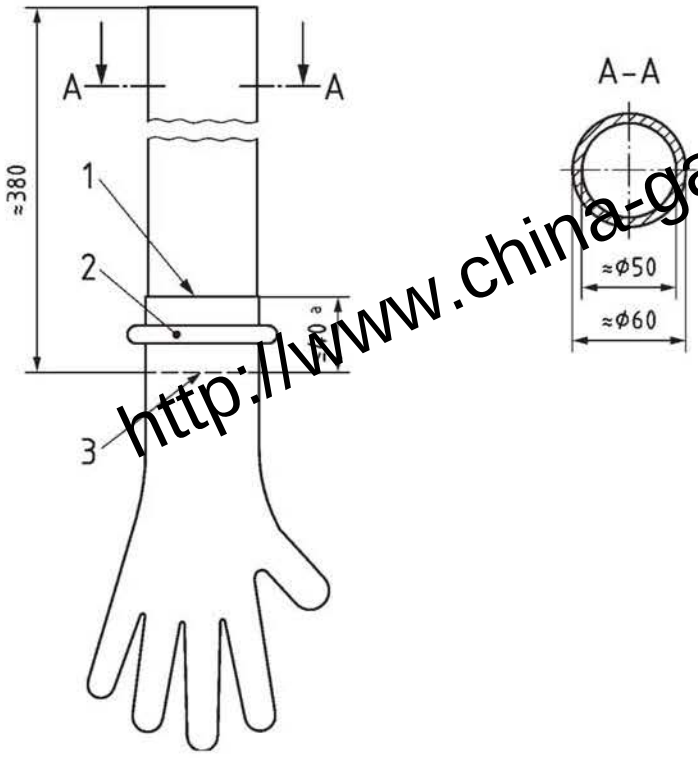
— the type of gloves and manufacturing batch code;

— 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
3 end of fill tube
a glove/fill tube overlap

Figure 1 — Water tightness test — Filling tube

Annex A
(informative)

Guidance on 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 to support the corresponding General Safety and Performance Requirements and to provide one voluntary means of conforming to Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117], the so called Medical Device Regulation (MDR).

This European Standard is suitable for conformity assessment purposes. Other means are possible.

NOTE 1 Currently for this European Standard there is no standardization request by the EU commission which is necessary to apply the harmonization procedure. An Annex ZA providing the presumption of conformity to the Medical Device Regulation (MDR) can therefore not be included in this document. Instead, this informative Annex has been included in order to provide at least the Table A.1 which conforms to the Table ZA.1 of the Annex ZA in both structure and content.]

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 A.1, it means that it is not addressed by this European Standard.

Table A.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
Chapter I, Clause 1.	4, 6	Safe design and high level of performance achieved by defining AQL limits of freedom from holes
Chapter I, Clause 4. (a)	4, 6	Safe design and man-ufacture through AQL limits of freedom from holes

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*

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