BSI Standards Publication

Medical gloves for single use

Part 1: Requirements and testing for freedom from holes

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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 It supersedes BS EN 455-1:2000, which is withdrawn.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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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

This European Standard was approved by CEN on 13 April 2020.

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Contents

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of an identical text or by endorsement, at the latest by November 2020, and conflicting national standards shall be withdrawn at the latest by November 2020.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.