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

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 455-1:2020+A2:2024 sisaldab Euroopa standardi EN 455-1:2020+A2:2024 ingliskeelset teksti.	This Estonian standard EVS-EN 455-1:2020+A2:2024 consists of the English text of the European standard EN 455-1:2020+A2:2024.
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 and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 18.09.2024.	Date of Availability of the European standard is 18.09.2024.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

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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English Version

Medical gloves for single use - Part 1: Requirements and testing for freedom of 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 16 December 2021 and includes Amendment 2 approved by CEN on 12 August 2024.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 455-1:2020+A2:2024) 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of an identical text or by endorsement, at the latest by March 2025, and conflicting national standards shall be withdrawn at the latest by March 2025.

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 ▌A2⟩ EN 455-1:2020+A1:2022 ⟨A2▌.

This document includes Amendment 1 approved by CEN on 23 February 2022 and Amendment 2 approved by CEN on 12 August 2024.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1⟩ ⟨A1▌ and ▌A2⟩ ⟨A2▌.

In comparison with the previous 2000 edition, the following main changes have been introduced to the 2020 edition:

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.

This document has been prepared under a standardisation request addressed to CEN and CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

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.

A list of all parts in a series can be found on the CEN website.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

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

A2 The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2859-1:1999,[1] *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection* A2

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 https://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

A1 **3.3**
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] A1

4 Requirement

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

[1] As impacted by ISO 2859-1:1999/Cor 1:2001 and ISO 2859-1:1999/Amd 1:2011.