SLOVENSKI STANDARD
SIST EN 455-1:2020+A2:2024

01-december-2024

Medicinske rokavice za enkratno uporabo - 1. del: Zahteve in preskusi za ugotavljanje odsotnosti lukenj (vključno z dopolnilom A2)

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

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

Gants médicaux non réutilisables - Partie 1 : Exigences et essais pour la détection de l'absence de trous

Ta slovenski standard je istoveten z: **EN 455-1:2020+A2:2024**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

SIST EN 455-1:2020+A2:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

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This European Standard was approved by CEN on 16 December 2021 and includes Amendment 2 approved by CEN on 12 August 2024.

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This European Standard exists 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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by March 2025, and conflicting national standards shall be withdrawn at the latest by March 2025.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.