SLOVENSKI STANDARD
SIST EN 455-1:2020+A1:2022/oprA2:2023

01-marec-2023

Medicinske rokavice za enkratno uporabo - 1. del: Zahteve in preskusi za ugotavljanje odsotnosti lukenj - Dopolnilo 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 - Partie1 : Exigences et essais pour la détection de l'absence de trous

Ta slovenski standard je istoveten z: **EN 455-1:2020+A1:2022/prA2:2023**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

SIST EN 455-1:2020+A1:2022/oprA2:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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EN 455-1:2020+A1:2022

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January 2023

ICS 11.140

English Version

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

Gants médicaux non réutilisables - Partie1 : Exigences et essais pour la détection de l'absence de trous

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

This draft amendment is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

This draft amendment A2, if approved, will modify the European Standard EN 455-1:2020+A1:2022. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment 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.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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+A1:2022/prA2:2023) 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 has been prepared under a Standardization Request given to CEN and CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For the relationship with EU Directive(s) / Regulation(s), 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.

1 Modifications to the European foreword

*Besides of the formal update of the existing European foreword of EN 455-1:2020+A1:2022 to include EN 455-1:2020+*prA2:2023*, due to the intended integration of an Annex ZA add the following text at the appropriate place:*

"This document has been prepared under a Standardization Request given to CEN and CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For the relationship with EU Directive(s) / Regulation(s), see informative Annex ZA, which is an integral part of this document."

and:

"In comparison with the previous version EN 455-1:2020+A1:2022 of edition EN 455-1:2020, the following main changes have been introduced:

a) replacement of Annex A with a new Annex ZA.".

2 Modification to Annex A, 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

Replace the existing Annex A with the following Annex ZA:

"

Annex ZA
(informative)

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

This European standard has been prepared under M/575 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] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

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.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

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.