



Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 455-1:2020+A1:2022

**Medical gloves for single use - Part 1:
Requirements and testing for freedom
from 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

02/2022



National Foreword

This European Standard EN 455-1:2020+A1:2022 was adopted as Luxembourgish Standard ILNAS-EN 455-1:2020+A1:2022.

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ILNAS-EN 455-1:2020+A1:2022

EUROPEAN STANDARD **EN 455-1:2020+A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2022

ICS 11.140

Supersedes EN 455-1:2020

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 and includes Amendment 1 approved by CEN on 16 December 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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

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) 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 August 2022, and conflicting national standards shall be withdrawn at the latest by August 2022.

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 455-1:2020 .

This document includes Amendment 1 approved by CEN on 23 February 2022.

The start and finish of text introduced or altered by amendment is indicated in the text by tags  .

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.

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.

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, Turkey and the United Kingdom.