

ILNAS

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

ILNAS-EN 455-3:2023

Medical gloves for single use - Part 3: Requirements and testing for biological evaluation

Gants médicaux non réutilisables - Partie
3 : Exigences et essais pour évaluation
biologique

Medizinische Handschuhe zum
einmaligen Gebrauch - Teil 3:
Anforderungen und Prüfung für die
biologische Bewertung

National Foreword

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ILNAS-EN 455-3:2023

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 455-3

November 2023

ICS 11.140

Supersedes EN 455-3:2015

English Version

**Medical gloves for single use - Part 3: Requirements and
testing for biological evaluation**

Gants médicaux non réutilisables - Partie 3 : Exigences
et essais pour évaluation biologique

Medizinische Handschuhe zum einmaligen Gebrauch -
Teil 3: Anforderungen und Prüfung für die biologische
Bewertung

This European Standard was approved by CEN on 29 October 2023.

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

Contents

	Page
European foreword.....	5
Introduction	7
1 Scope.....	8
2 Normative references.....	8
3 Terms and definitions	8
4 Requirements	9
4.1 General.....	9
4.2 Chemicals	9
4.3 Endotoxins.....	10
4.4 Powder-free gloves.....	10
4.5 Proteins, leachable	10
4.6 Labelling.....	10
5 Test methods	12
5.1 Endotoxins.....	12
5.2 Powder	12
5.3 Proteins, leachable	12
6 Test report.....	13
Annex A (normative) Method for the determination of aqueous extractable proteins in natural rubber gloves using the modified Lowry assay	14
A.1 General.....	14
A.2 Principle	14
A.3 Reagents	14
A.4 Apparatus.....	15
A.5 Measurement of protein binding capacity	16
A.5.1 General.....	16
A.5.2 Protein binding capacity of centrifuge tubes	16
A.5.3 Protein binding capacity of filter units	17
A.6 Procedure.....	17
A.6.1 General.....	17
A.6.2 Extraction procedure.....	18
A.6.3 Protein standard	18
A.6.4 Precipitation and concentration of protein.....	19
A.6.5 Colour development.....	19
A.6.6 Measurement.....	20
A.7 Expression of results.....	20
A.7.1 Calculation	20
A.7.2 Results.....	20

A.7.3 Statistical information	22
A.8 References.....	23
Annex B (informative) Immunological methods for the measurements of natural rubber latex allergens.....	24
B.1 General	24
B.2 Natural rubber latex allergens in manufactured rubber products	24
B.3 Methods for measuring natural rubber latex allergens	25
B.3.1 Qualitative methods	25
B.3.2 Semiquantitative methods	25
B.3.3 Specific quantitative methods.....	26
B.4 Conclusion	27
B.5 References.....	27
Annex C (informative) Amino acid analysis (AAA) by high pressure liquid chromatography (HPLC).....	30
C.1 Background.....	30
C.2 Principles of the determination of proteins by HPLC.....	30
C.3 Material	30
C.4 Buffers and solutions	31
C.4.1 Norvalin-100	31
C.4.2 Norvalin-1.....	31
C.4.3 o-Phthaldialdehyde (OPA).....	31
C.4.4 Boratebuffer	31
C.4.5 Stop-solution	32
C.4.6 Phosphate buffer.....	32
C.4.7 Solvent 1.....	32
C.4.8 Solvent 2.....	32
C.4.9 Sodium carbonate solution (0,1 M).....	32
C.5 Hydrolysis.....	32
C.5.1 Samples	32
C.5.2 Standards.....	32
C.5.3 Incubation (hydrolysis).....	32
C.5.4 Free amino acids	32
C.6 Analysis (HPLC)	32
C.6.1 Sample preparation	32
C.6.2 Derivatisation	33
C.6.3 HPLC	33
C.6.4 Calculation.....	33

C.7 Examples	33
C.7.1 Standard	33
C.7.2 Glove extract	34
C.8 Advantages and disadvantages of the HPLC method.....	34
C.8.1 Advantages	34
C.8.2 Disadvantages	34
C.9 References	37
Annex ZA (informative) Relationship between this European standard and General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered.....	39
Bibliography.....	42

European foreword

This document (EN 455-3:2023) 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 May 2024, and conflicting national standards shall be withdrawn at the latest by November 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 EN 455-3:2015.

Compared to the previous edition EN 455-3:2015 the following main changes have been introduced:

- a) update of Clause 3 'Terms and definitions';
- b) update of Clause 4 'Requirements' especially in regard of the subclauses 'Chemicals', 'Endotoxins' and 'Labelling';
- c) clarification of 5.3, NOTE 2
- d) update of Clause 6 'Test report'
- e) alignment of Annex ZA to the MDR;
- f) complete editorial revision.

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.

This document has been prepared under a standardization request addressed to CEN 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.

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.

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