

DIN EN 455-3:2024-02 (E)

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

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
--------------------	----