

DIN EN 455-3:2015-07 (E)

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

Contents	Page
Foreword	3
Introduction	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Requirements	7
4.1 General	7
4.2 Chemicals	7
4.3 Endotoxins	8
4.4 Powder-free gloves	8
4.5 Proteins, leachable	8
4.6 Labelling	8
5 Test methods	9
5.1 Endotoxins	9
5.2 Powder	9
5.3 Proteins, leachable	9
6 Test report	9
Annex A (normative) Method for the determination of aqueous extractable proteins in natural rubber gloves using the modified Lowry assay	10
Annex B (informative) Immunological methods for the measurements of natural rubber latex allergens	20
Annex C (informative) Amino acid analysis (AAA) by high pressure liquid chromatography (HPLC)	26
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical Devices	34