

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

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

---

| <b>Contents</b>   |                             | <b>Page</b> |
|---|-----------------------------|-------------|
| 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          |