

# ISO 8871-1:2003-10 (E)

## Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 1: Extractables in aqueous autoclavates

---

| <b>Contents</b>   | <b>Page</b> |
|---|-------------|
| Foreword .....  | iv          |
| Introduction .....  | v           |
| 1 <b>Scope</b> .....                                      | 1           |
| 2 <b>Normative references</b> .....                       | 1           |
| 3 <b>Classification</b> .....                             | 2           |
| 4 <b>Requirements</b> .....                               | 2           |
| 5 <b>Sampling</b> .....                                   | 2           |
| 6 <b>Apparatus and reagents</b> .....                     | 3           |
| 7 <b>Preparation of test solutions</b> .....              | 4           |
| <b>Annex A (normative) Appearance of solution</b> .....   | 5           |
| <b>Annex B (normative) Acidity or alkalinity</b> .....    | 9           |
| <b>Annex C (normative) Absorbance</b> .....               | 10          |
| <b>Annex D (normative) Reducing substances</b> .....      | 11          |
| <b>Annex E (normative) Extractable heavy metals</b> ..... | 12          |
| <b>Annex F (normative) Extractable zinc</b> .....         | 14          |
| <b>Annex G (normative) Extractable ammonia</b> .....      | 15          |
| <b>Annex H (normative) Residue on evaporation</b> .....   | 16          |
| <b>Annex I (normative) Volatile sulfides</b> .....        | 17          |
| <b>Annex J (informative) Conductivity</b> .....           | 18          |
| <b>Bibliography</b> .....                                 | 19          |