

# DIN EN ISO 8536-2:2010-08 (E)

## Infusion equipment for medical use - Part 2: Closures for infusion bottles (ISO 8536-2:2010)

---

| <b>Contents</b>                                                    | <b>Page</b> |
|--------------------------------------------------------------------|-------------|
| Foreword .....                                                     | 3           |
| Introduction .....                                                 | 4           |
| 1      Scope .....                                                 | 5           |
| 2      Normative references .....                                  | 5           |
| 3      Shape and dimensions .....                                  | 5           |
| 4      Designation .....                                           | 7           |
| 5      Material .....                                              | 7           |
| 6      Requirements .....                                          | 7           |
| 6.1    General .....                                               | 7           |
| 6.2    Physical requirements .....                                 | 7           |
| 6.3    Chemical requirements .....                                 | 8           |
| 6.4    Biological requirements .....                               | 8           |
| 7      Labelling .....                                             | 8           |
| Annex A (normative) Determination of fragments .....               | 9           |
| Annex B (normative) Determination of spike penetration force ..... | 11          |
| Annex C (normative) Spike retention/sealability .....              | 13          |
| Annex D (normative) Closure piercing device .....                  | 14          |
| Bibliography .....                                                 | 15          |