

ISO 11040-7:2015-04 (E)

Prefilled syringes - Part 7: Packaging systems for sterilized subassembled syringes ready for filling

| Contents | | Page |
|---|--|-------------|
| Foreword | | iv |
| Introduction | | v |
| 1 | Scope | 1 |
| 2 | Normative references | 1 |
| 3 | Terms and definitions | 1 |
| 4 | Requirements for the packaging system | 2 |
| 4.1 | General | 2 |
| 4.2 | Nest | 3 |
| 4.3 | Tub | 4 |
| 4.4 | Insert liner | 4 |
| 4.5 | Sealing lid | 4 |
| 4.6 | Protective bag | 5 |
| 5 | Information to be provided by the manufacturer | 5 |
| 6 | Marking of the tub | 5 |
| 7 | Packaging of tubs in trading units/bundles | 6 |
| Annex A (informative) Design of nests | | 7 |
| Annex B (informative) Determination of nest deflection | | 14 |
| Annex C (informative) Design of tubs | | 17 |
| Annex D (informative) Schematic illustrations of examples for the orientation of tubs within the protective bag | | 19 |
| Annex E (informative) Design and dimensions of the protective bag | | 21 |
| Annex F (informative) Test method to determine the distance between the edge of the protective bag to the rear end of the tub | | 24 |
| Bibliography | | 27 |