

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