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