

ISO 15759:2005-04 (E)

Medical infusion equipment - Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (B FS) process

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Dimensions and designation	2
3.1	Plastics cap for attachment by welding technique (Form A)	2
3.2	Plastics cap for attachment by collar technique (Form B)	3
3.3	Elastomeric liner	4
4	Materials for cap and liner	4
5	Plastics cap -- Physical requirements and testing	5
5.1	Leak-resistance test	5
5.2	Opening force	5
6	Liner -- Physical requirements and testing	5
6.1	General requirements	5
6.2	Hardness	5
6.3	Fragmentation (coring)	5
6.4	Penetration force	5
6.5	Dynamic spike-retention capability	5
6.6	Static spike-retention capability of the liner and leak resistance of the piercing area	5
6.7	Resealability	5
7	Plastics cap -- Chemical requirements and testing	5
8	Liner -- Chemical requirements and testing	6
9	Biological requirements for plastics cap and liner	6
10	Packaging	6
11	Storage	6
12	Marking	6
Annex A (normative)	Leak-resistance test	7
Annex B (normative)	Opening force needed to expose the piercing area	8
Annex C (normative)	Fragmentation (coring)	9
Annex D (normative)	Penetration force	10
Annex E (normative)	Dynamic spike retention capability	12

Annex F (normative) Static spike-retention capability of the liner and leak resistance of the piercing area	13
Annex G (normative) Resealability	14
Annex H (normative) Holding device for elastomeric liner	15
Annex I (normative) Reference spike	16
Bibliography	17