

ISO 3826-4:2015-08 (E)

Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Dimensions	4
5	Design	10
5.1	Leucocyte filter	10
5.2	Pilot samples	10
5.3	Access line needle and return line needle	11
5.4	Needle stick protection device	11
5.5	Pre-collection sampling device	11
5.6	Red blood cell storage bag	11
5.7	Plasma storage bag	12
5.8	Platelet storage bag	12
5.9	Post-collection sampling device	12
5.10	Collection and transfer tube(s)	12
5.11	Outlet port(s)	13
5.12	Suspension	13
6	Requirements	13
6.1	General	13
6.2	Physical requirements	14
6.2.1	Conditions of manufacture	14
6.2.2	Sterilization	14
6.2.3	Transparency	14
6.2.4	Coloration	14
6.2.5	Thermal stability	14
6.2.6	Water vapour transmission for plastics containers prefilled with storage solution or anticoagulant	14
6.2.7	Resistance to leakage	15
6.2.8	Insertion force	15
6.2.9	Pull force	15
6.2.10	Leakage after closure piercing	15
6.2.11	Particulate contamination	15
6.3	Chemical requirements	16
6.3.1	Requirements for the raw container or sheeting	16
6.3.2	Requirements for the test fluid	16
6.4	Biological requirements	17
6.4.1	General	17
6.4.2	Impermeability for microorganisms	17
6.4.3	Compatibility	17
7	Packaging	17
7.1	General	17

7.2	Shelf-life	17
7.3	Over-package materials	17
7.4	Over-package sealing	17
7.5	Over-package strength	18
7.6	Arrangement of components in the over-package	18
8	Labelling	18
8.1	General	18
8.2	Label on plastics containers	18
8.3	Label on over-package	18
8.4	Package insert or instructions for use	19
8.5	Label on shipping box	19
8.6	Label requirements	20
9	Anticoagulant and/or preservative solution	20
Annex A (normative) Chemical tests		21
Annex B (normative) Physical tests		26
Annex C (normative) Biological tests		28
Bibliography		31