DIN EN ISO 3826-4:2015-12 (E)

Plastics collapsible containers for human blood and blood components - Part 4: Apheresis blood bag systems with integrated features (ISO 3826-4:2015)

Contents

Page

European foreword ... **4**

Introduction ... **6**

1 Scope ... **7**

2 Normative references ... **7**

3 Terms and definitions ... **8**

4 Dimensions ... **10**

5 Design ... **16**
5.1 Leucocyte filter ... 16
5.2 Pilot samples ... 16
5.3 Access line needle and return line needle ... 17
5.4 Needle stick protection device ... 17
5.5 Pre-collection sampling device ... 17
5.6 Red blood cell storage bag ... 17
5.7 Plasma storage bag ... 18
5.8 Platelet storage bag ... 18
5.9 Post-collection sampling device ... 18
5.10 Collection and transfer tube(s) ... 18
5.11 Outlet port(s) ... 19
5.12 Suspension ... 19

6 Requirements ... **19**
6.1 General ... 19
6.2 Physical requirements ... 20
6.2.1 Conditions of manufacture ... 20
6.2.2 Sterilization ... 20
6.2.3 Transparency ... 20
6.2.4 Coloration ... 20
6.2.5 Thermal stability ... 20
6.2.6 Water vapour transmission for plastics containers prefilled with storage solution or anticoagulant ... 20
6.2.7 Resistance to leakage ... 21
6.2.8 Insertion force ... 21
6.2.9 Pull force ... 21
6.2.10 Leakage after closure piercing ... 21
6.2.11 Particulate contamination ... 21
6.3 Chemical requirements ... 22
6.3.1 Requirements for the raw container or sheeting ... 22
6.3.2 Requirements for the test fluid ... 22
6.4 Biological requirements ... 23
6.4.1 General ... 23
6.4.2 Impermeability for microorganisms ... 23
6.4.3 Compatibility ... 23

7 Packaging **23**
7.1 General 23
7.2 Shelf-life 23
7.3 Over-package materials 23
7.4 Over-package sealing 23
7.5 Over-package strength 24
7.6 Arrangement of components in the over-package 24
8 Labelling **24**
8.1 General 24
8.2 Label on plastics containers 24
8.3 Label on over-package 24
8.4 Package insert or instructions for use 25
8.5 Label on shipping box 25
8.6 Label requirements 26
9 Anticoagulant and/or preservative solution **26**
Annex A (normative) **Chemical tests** **27**
Annex B (normative) **Physical tests** **32**
Annex C (normative) **Biological tests** **34**
Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical devices** **37**
Bibliography **39**