

DIN EN ISO 3826-1:2020-01 (E)

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers (ISO 3826-1:2019)

Contents

	Page
European foreword	3
Foreword	4
Introduction	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Dimensions	7
5 Design	7
5.1 General	7
5.2 Air content	8
5.3 Emptying under pressure	8
5.4 Pilot samples	8
5.5 Rate of collection	8
5.6 Collection and transfer tube(s)	10
5.7 Blood-taking needle	11
5.8 Outlet port(s)	11
5.9 Suspension	12
6 Requirements	12
6.1 General	12
6.2 Physical requirements	12
6.2.1 Conditions of manufacture	12
6.2.2 Sterilization	12
6.2.3 Transparency	12
6.2.4 Coloration	13
6.2.5 Thermal stability	13
6.2.6 Water vapour transmission	13
6.2.7 Resistance to leakage	13
6.2.8 Particulate contamination	13
6.3 Chemical requirements	14
6.3.1 Requirements for the raw container or sheeting	14
6.3.2 Requirements for the test fluid	14
6.4 Biological requirements	15
6.4.1 General	15
6.4.2 Impermeability for microorganisms	15
6.4.3 Compatibility	15
7 Packaging	15
8 Labelling	15
8.1 General	15
8.2 Label on plastics container	16
8.3 Label on over-package	16
8.4 Label on shipping box	17
8.5 Label requirements	17
9 Anticoagulant and/or preservative solution	17
Annex A (normative) Chemical tests	18
Annex B (normative) Physical tests	23
Annex C (normative) Biological tests	25
Bibliography	28