

DIN EN 1820:2009-12 (E)

Anaesthetic reservoir bags (ISO 5362:2000, modified) (includes Amendment A1:2009)

Contents		Page
Foreword		4
Introduction		5
1 Scope		6
2 Normative references		6
3 Terms and definitions		6
4 General requirements		7
5 Prevention of electrostatic charges		9
6 Requirements for bags supplied sterile		9
7 Marking		9
8 Information to be supplied by the manufacturer		10
Annex A (informative) Test for leakage		11
A.1 Principle		11
A.2 Apparatus		11
A.3 Procedure		11
A.4 Expression of results		11
Annex B (normative) Determination of capacity		12
B.1 Principle		12
B.2 Apparatus		12
B.3 Procedure		12
B.4 Expression of results		12
Annex C (normative) Test for security of attachment of plain neck to 22 mm male conical connector 13 C.1 Principle		13
C.2 Apparatus and materials		13
C.3 Procedure		13
Annex D (normative) Test for security of attachment of adaptor of assembled neck to bag		14
D.2 Apparatus		14
D.3 Procedure		14
Annex E (normative) Test for resistance to pressure required to distend the bag (pressure/volume). 15 E.1 Principle		15
E.2 Apparatus		15
E.3 Procedure		15
E.4 Expression of results		15

Annex F (informative) Test for resistance to pressure required to distend the bag using air (pressure/volume)	16
F.1 Principle	16
F.2 Apparatus	16
F.3 Procedure	16
F.4 Expression of results	16
Annex G (informative) Recommendations for materials	17
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical devices	18
Bibliography	20