

DIN EN ISO 15747:2019-07 (E)

Plastic containers for intravenous injections (ISO 15747:2018)

Contents	Page
European foreword.....	3
Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered.....	5
Foreword.....	7
1 Scope	8
2 Normative references	8
3 Terms and definitions.....	8
4 Requirements.....	9
4.1 Physical requirements.....	9
4.1.1 Manufacturing process compatibility	10
4.1.2 Resistance to temperature, pressure and leakage	10
4.1.3 Resistance to dropping.....	10
4.1.4 Transparency	10
4.1.5 Water vapour permeability	10
4.1.6 Particulate contamination.....	10
4.1.7 Cover.....	10
4.1.8 Access port — Penetration ability of the insertion point.....	10
4.1.9 Access port — Adhesion strength of the infusion device and impermeability of the insertion point.....	10
4.1.10 Access port — Tightness of the injection point.....	11
4.1.11 Hanger	11
4.1.12 Identification.....	11
4.2 Chemical requirements	11
4.2.1 Requirements for the raw container or the sheeting.....	11
4.2.2 Requirements for the test fluid	11
4.3 Biological requirements.....	12
4.3.1 Impermeability for microorganisms.....	12
4.3.2 Migration	12
5 Application of tests.....	12
Annex A (normative) Physical tests.....	13
Annex B (normative) Chemical tests.....	16
Annex C (normative) Biological tests.....	19
Annex D (normative) Reference spike.....	21
Bibliography.....	23