

### Contents

Page

Foreword .....	iv
1 Scope .....	1
2 Normative references .....	1
3 General requirements .....	1
4 Designation .....	4
4.1 Infusion set .....	4
4.2 Air-inlet device .....	4
5 Materials .....	4
6 Physical requirements .....	5
6.1 Particulate contamination .....	5
6.2 Leakage .....	5
6.3 Tensile strength .....	5
6.4 Closure-piercing device .....	5
6.5 Air-inlet device .....	5
6.6 Tubing .....	6
6.7 Fluid filter .....	6
6.8 Drip chamber and drip tube .....	6
6.9 Flow regulator .....	6
6.10 Flow rate of infusion fluid .....	6
6.11 Injection site .....	6
6.12 Male conical fitting .....	6
6.13 Protective caps .....	6
7 Chemical requirements .....	7
7.1 Reducing (oxidizable) matter .....	7
7.2 Metal ions .....	7
7.3 Titration acidity or alkalinity .....	7
7.4 Residue on evaporation .....	7
7.5 UV absorption of extract solution .....	7
8 Biological requirements .....	7
8.1 General .....	7
8.2 Sterility .....	7
8.3 Pyrogenicity .....	7
8.4 Haemolysis .....	7
8.5 Toxicity .....	8
9 Labelling .....	8
9.1 Unit container .....	8
9.2 Shelf or multi-unit container .....	8
10 Packaging .....	9
Annex A (normative) Physical tests .....	10
Annex B (normative) Chemical tests .....	14
Annex C (normative) Biological tests .....	16
Bibliography .....	17