

DIN EN ISO 22413:2011-08 (E)

Transfer sets for pharmaceutical preparations - Requirements and test methods (ISO 22413:2010)

Contents		Page
Foreword		4
Introduction		5
1	Scope	6
2	Normative references	6
3	Design and designation	6
3.1	Design	6
3.2	Design for a transfer set with housing	9
3.3	Designation	9
4	Material	9
5	Physical requirements	10
5.1	Particulate contamination	10
5.2	Tensile strength	10
5.3	Tightness	10
5.4	Free flow	10
5.5	Piercing device	10
5.6	Penetration force	10
5.7	Fragmentation	11
5.8	Air inlet and air outlet	11
5.9	Protective caps	11
5.10	Transfer sets with a housing	11
5.11	Luer connector	11
5.12	Filter for particles	11
6	Chemical requirements	11
7	Biological requirements	11
8	Testing of physical requirements	11
8.1	Particulate contamination	11
8.2	Tensile strength	12
8.3	Tightness of transfer set	12
8.4	Free flow	12
8.5	Piercing device	12
8.6	Penetration force	12
8.7	Testing on fragmentation	12
8.8	Effectiveness of air inlet and air outlet with air filter	12
8.9	Efficiency of protective caps	12
8.10	Luer connector	12
8.11	Filter for particles	12
9	Testing of chemical requirements	13
10	Testing of biological requirements	13
11	Packaging	13

12	Storage	13
13	Labelling	13
13.1	Unit container	13
13.2	Shelf or multi-unit container	13
Annex A (normative) Testing of fragmentation of transfer sets with plastic piercing devices		14
Annex B (normative) Testing of fragmentation of transfer sets with metal piercing devices		16
Bibliography		18
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EC Directive 93/42/EEC on medical devices		19