

DIN EN ISO 8536-12:2021-05 (E)

Infusion equipment for medical use - Part 12: Check valves for single use (ISO 8536-12:2021)

Contents		Page
European foreword		3
Foreword		4
1	Scope	5
2	Normative references	5
3	Terms and definitions	5
4	Designation	6
5	Materials	6
6	Physical requirements	6
6.1	Particulate contamination	6
6.2	Leakage	6
6.3	ISO 80369 (all parts) compatibility	6
6.4	Counterflow pressure resistance	6
6.5	Flow rate	7
6.6	Blocking performance	7
6.7	Opening pressure	7
6.8	Protective caps	7
7	Chemical requirements	7
8	Biological requirements	7
8.1	General	7
8.2	Sterility	7
8.3	Pyrogenicity	7
9	Labelling	7
9.1	General	7
9.2	Label on unit container	8
9.3	Label on shelf or multi-unit container	8
10	Packaging	8
11	Disposal	8
Annex A (normative) Physical tests		9
Bibliography		15