# 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 Termsanddefinitions ..... 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