DIN EN ISO 8536-15:2023-06 (E)

Infusion equipment for medical use - Part 15: Light-protective infusion sets for single use (ISO 8536-15:2022 + Amd 1:2023) (includes Amendment A1:2023)

Contents

Page

European foreword ... **3**

[A1] European foreword to Amendment [A1] ... **4**

Foreword ... **5**

[A1] Foreword to Amendment [A1] ... **6**

Introduction ... **7**

1 Scope ... **8**

2 Normative references ... **8**

3 Terms and definitions ... **8**

4 General requirements ... **8**

5 Materials ... **8**

6 Physical requirements ... **9**

6.1 General ... 9

6.2 Transparency ... 9

6.3 Light-protective performance ... 9

6.4 Decolourization ... 9

7 Chemical requirements ... **9**

8 Biological requirements ... **9**

9 Labelling ... **10**

10 Packaging ... **10**

11 Disposal ... **10**

Annex A (normative) **Determination of light transmittance** ... **11**

Annex B (normative) **Decolourization test – physical method** ... **13**

Annex C (normative) **Chemical method for decolourization test – visual colorimetry** ... **14**

Bibliography ... **15**