DIN EN ISO 7886-3:2020-10 (E)

Sterile hypodermic syringes for single use - Part 3: Auto- disabled syringes for fixed-dose immunization (ISO 7886-3:2020)

Contents

Page

European foreword ... **4**

Foreword ... **5**

Introduction ... **6**

1 Scope ... **7**

2 Normative references ... **7**

3 Terms and definitions ... **7**

4 Nomenclature ... **8**

5 General requirements ... **9**

6 Extraneous matter ... **10**
6.1 General ... 10
6.2 Limits for acidity or alkalinity ... 10
6.3 Limits for extractable metals ... 10

7 Lubricant ... **10**

8 Tolerance on nominal capacity ... **10**

9 Graduated scale ... **11**
9.1 Scale ... 11
9.2 Position of scale ... 11

10 Barrel ... **11**
10.1 Dimensions ... 11
10.2 Barrel flanges ... 11

11 Plunger stopper/plunger assembly ... **11**
11.1 Design ... 11
11.2 Fit of the plunger stopper/plunger in the barrel ... 12
11.3 Fiducial line ... 12

12 Needle ... **12**
12.1 General ... 12
12.2 Integrated needle ... 12
12.3 Non-integrated needle ... 12
12.4 Sharps protection features ... 12

13 Performance ... **13**
13.1 General ... 13
13.2 Dead space ... 13
13.3 Freedom from air and liquid leakage ... 13
13.4 Auto-disable syringe feature ... 13
13.5 Performance after shipping ... 13

14 Packaging ... **14**
14.1 Unit packaging providing sterile barrier ... 14
14.2 Multiple unit pack ... 14
14.3 User packaging ... 14

15 Information supplied by the manufacturer **14**
15.1 General 14
15.2 Syringes 14
15.3 Unit packaging providing sterile barrier 14
15.4 User packaging 15
15.5 Storage containers 15
15.6 Transport wrapping 16
Annex A (normative) **Method for preparation of extracts** **17**
Annex B (informative) **Test method for forces required to operate piston** **18**
Annex C (normative) **Test method for testing auto-disable syringe feature** **20**
Bibliography **21**