INTERNATIONAL STANDARD

ISO 7886-4

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Sterile hypodermic syringes for single use —

Part 4: Syringes with re-use prevention feature

Seringues hypodermiques stériles, non réutilisables —
Partie 4: Seringues avec dispositif empêchant la réutilisation

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 7886-4 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

ISO 7886 consists of the following parts, under the general title *Sterile hypodermic syringes for single use*:

— *Part 1: Syringes for manual use*

— *Part 2: Syringes for use with power-driven syringe pumps*

— *Part 3: Auto-disable syringes for fixed-dose immunization*

— *Part 4: Syringes with re-use prevention feature*

Introduction

The preparation of this part of ISO 7886 was recognized as a high priority requirement to prevent the re-use of syringes in the developing and transitional countries. Re-use of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens. See Reference [1] in the Bibliography.

The World Health Organisation had produced a specification for syringes that are rendered inactive after use (commonly referred to as “auto-disable” syringes) for fixed dose immunization and syringes with re-use prevention features for general purpose. Both the WHO and ISO agreed that additional parts of ISO 7886 would be required to cover syringes with re-use prevention features, whilst leaving in place ISO 7886-1 and ISO 7886-2 without modification, as a large number of devices in common use would not be intended to comply with the re-use prevention properties suggested.

This part of ISO 7886 is intended to cover syringes that are rendered inoperable after delivery of the intended dose. These syringes are not covered by ISO 7886-1 and ISO 7886-3. ISO 7886-2 covers syringes used with power-driven pumps. Given the diversity of clinical applications, the most appropriate re-use prevention feature offering the highest level of re-use prevention is to be considered for each specific intended use.

It is recognized that syringes designed to reduce the risk of needlestick injuries can also comply with this part of ISO 7886 with regard to their re-use prevention properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in this part of ISO 7886.

Sterile hypodermic syringes for single use —

Part 4:
Syringes with re-use prevention feature

1 Scope

This part of ISO 7886 specifies requirements for sterile single-use hypodermic syringes made of plastics materials with or without needle, and intended for the aspiration of fluids or for the injection of fluids immediately after filling and of design such that the syringe can be rendered unusable after use.

This part of ISO 7886 is not applicable to syringes made of glass (specified in ISO 595), auto-disable syringes for fixed dose immunization (ISO 7886-3) and syringes designed to be pre-filled. It does not address compatibility with injection fluids. Other standards can be applicable when syringes are used for any other intended purpose than those specified in this part of ISO 7886.

NOTE Syringes designed to reduce the risk of needlestick injuries can also comply with this part of ISO 7886 with regard to their re-use prevention properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in this part of ISO 7886.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 780, *Packaging — Pictorial marking for handling of goods*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7864:1993, *Sterile hypodermic needles for single use*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8537:1991, *Sterile single-use syringes, with or without needle, for insulin*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

ASTM D999-01, *Standard methods for vibration testing of shipping containers*

ASTM D5276-98, *Standard test method for drop test of loaded containers by free fall*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7886-1, ISO 8537 and the following apply.

3.1
re-use prevention feature
feature that either automatically activates upon or during administration of the intended dose or is activated by the user to prevent subsequent re-use of the syringe

4 Nomenclature

The nomenclature for components of syringes with re-use prevention feature is shown in Figure 1.

5 Types of syringe

5.1 General

Syringe types shall be categorized in accordance with 5.2 and 5.3.

Given the diversity of clinical applications, the most appropriate re-use prevention feature offering the highest level of re-use prevention should be considered for each specific intended use.

5.2 Re-use prevention feature

The re-use prevention feature shall be categorized as follows;

— **Type 1**: operates automatically during or upon completion of intended single use;

— **Type 2**: requires elective activation upon completion of intended single use.

5.3 Intended use/application

The intended use/application shall be categorized as follows;

— **Type A**: single aspiration and injection;

— **Type B**: multiple plunger aspirations prior to the final intended single use.

6 Cleanliness

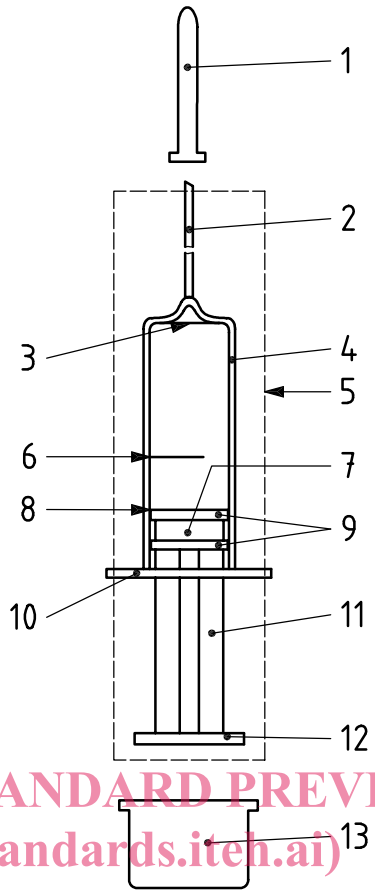
The requirements of Clause 5 of ISO 7886-1:1993 apply.

7 Limits for acidity or alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with Annex A shall be within one unit of pH of that of the control fluid.

8 Limits for extractable metals

When tested by a recognized microanalytical method, for example by an atomic absorption method, an extract prepared in accordance with Annex A shall, when corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0,1 mg/l.



Key

1 needle cap/protective end cap (if used)
2 needle
3 zero line
4 barrel
5 re-use prevention feature
6 nominal capacity line
7 piston
8 fiducial line
9 seal(s)
10 finger grips
11 plunger
12 push-button
13 protective end cap (if used)

NOTE 1 The syringe can have graduated scale lines in accordance with ISO 7886-1.

NOTE 2 This illustration can be considered as reference for nomenclature of components. The configuration and design can vary with the design of syringe.

NOTE 3 The drawing is intended to be illustrative of components of a syringe with a re-use prevention feature.

Figure 1 — Schematic representation of a syringe with re-use prevention feature

9 Lubricant

The requirements of Clause 8 of ISO 7886-1:1993 and 11.4 of ISO 7864:1993 apply.

10 Tolerance on graduated capacity

The tolerances on the graduated capacity shall be as given in ISO 7886-1:1993, Table 1 or, for insulin syringes, shall be as given in reference ISO 8537:1991, Table 1.

11 Graduated scale

11.1 Scale

Graduated scales shall comply with 10.1 of ISO 7886-1:1993 or 9.1 of ISO 8537:1991.

11.2 Numbering of scale

The requirements of 10.2 of ISO 7886-1:1993 or 9.2 of ISO 8537:1991 apply as appropriate.

11.3 Position of scale

The requirements of 10.4 of ISO 7886-1:1993 apply.

11.4 Overall length of scale to nominal capacity line

The requirements of 10.3 of ISO 7886-1:1993 or 9.3 of ISO 8537:1991 apply except for fixed dose scales.

12 Barrel

12.1 Dimensions

The length of the barrel and the design of the re-use prevention feature shall be such that the syringe has a recommended maximum usable capacity of at least 5 % more than the nominal capacity and a recommended maximum capacity of 20 % more that the nominal capacity.

12.2 Finger grips

The requirements of 11.2 of ISO 7886-1:1993 apply.

13 Piston/plunger assembly

13.1 Design

The design of the plunger and push-button of the syringe shall be such that, when the barrel is held in one hand, the plunger can be depressed by the thumb of that hand. When a syringe with integrated needle is tested in accordance with Annex B of ISO 8537:1991 or a syringe without needle is tested in accordance with Annex B of ISO 7886-1:1993, the piston shall not inadvertently become detached from the plunger during intended use. The projection of the plunger and the configuration of the push-button should be such as to allow the plunger to be operated without difficulty. When the plunger is positioned to begin the filling process, the preferred minimum length of the plunger from the surface of the finger grips should be:

a) 8 mm for syringes of nominal capacity up to, but excluding, 2 ml;

b) 9 mm for syringes of nominal capacity of 2 ml up to, but excluding, 5 ml;

c) 12,5 mm for syringes of nominal capacity of 5 ml and greater.

13.2 Fit of the piston in the barrel

For general use syringes, the requirements of 12.2 of ISO 7886-1:1993 apply. For insulin syringes, 11.3 of ISO 8537:1991 applies.

13.3 Fiducial line

The requirements of 12.3 of ISO 7886-1:1993 or 11.3 of ISO 8537:1991 apply as appropriate.

14 Syringe nozzle/needle

14.1 Syringe with integrated needle

Syringes with integrated needle shall have a minimum needle union force applied as pull in the direction of the needle axis in accordance with ISO 7864:1993.

Needle tubing shall be in accordance with ISO 9626.

14.2 Syringe with Luer nozzle

Syringes with male conical fittings shall be in accordance with Clause 13 of ISO 7886-1:1993.

15 Performance

15.1 Dead space

When tested in accordance with Annex E of ISO 8537:1991, the dead space shall not exceed the limits specified in 14.1 of ISO 7886-1:1993. This dead space requirement refers to syringes without needles attached; for syringes supplied with attached needles, the dead space volume of the needle shall be subtracted.

15.2 Freedom from air and liquid leakage

When syringes with integrated needles are tested in accordance with Annex F of ISO 8537:1991 and syringes without needles are tested in accordance with Annex D of ISO 7886-1:1993, there shall be no leakage of water past the piston or seal(s).

When syringes with integrated needles are tested in accordance with Annex B of ISO 8537:1991 and syringes without needles are tested in accordance with Annex B of ISO 7886-1:1993, there shall be no leakage of air past the piston or seal(s), and there shall be no fall in the manometer reading.

For syringes with integrated needles, the requirements of 14.2 of ISO 8537:1991 apply.

Leakage resistance should be demonstrated irrespective of the re-use prevention feature.

15.3 Re-use prevention feature

Once the re-use prevention feature has been activated in accordance with the manufacturer's instruction, it shall not be possible to re-use the syringe under the normal conditions of use, or by testing in accordance with the test method in Annex B.