INTERNATIONAL STANDARD

ISO 7886-3

Second edition
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Sterile hypodermic syringes for single use —

Part 3: Auto-disabled syringes for fixed-dose immunization

Seringues hypodermiques stériles, non réutilisables —

Partie 3: Seringues autobloquantes pour vaccination à dose fixe

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 7886-3:2005), which has been technically revised. The main changes compared to the previous edition are as follows:

— update of the references, mainly ISO 7886-1:2017.

A list of all parts in the ISO 7886 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 7886 was first published in 1984. It was subsequently decided to divide it into two parts: ISO 7886-1 retaining essentially the scope of ISO 7886:1984 and ISO 7886-2 being applicable to sterile, single-use syringes for use with power-driven pumps.

The preparation of this document was recognized as a high priority to prevent the reuse of fixed dose immunization syringes. Reuse of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens.

The World Health Organization (WHO) had produced a specification for syringes that are rendered inactive after one use (commonly referred to as "auto-disabled" syringes). It was agreed that an additional part of the ISO 7886 series would be needed to cover "auto-disabled" syringes, while 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 conform with the auto-disable properties suggested.

It has been discussed to limit the syringe types to only comprise the type having an auto-disable syringe feature that is automatically activated and remains effective from the time that the injection is commenced. An assessment of potential hazards based only on hypothetical use indicates that the type having an auto-disable syringe feature that is automatically activated and remains effective from the time of the injection being initiated is potentially safer than the other types. However, no consensus could be reached on either deleting types or retaining them, as no reliable risk data from field use exists at present. It was therefore agreed to retain all types and restrict this revision to alignment with ISO 7886-1:2017 and initiate a new revision if new field studies or incident reports indicate a need for a revision.

It is recognized that syringes designed to reduce the risk of needle stick injuries can also conform with this document.

In some countries national regulations might take precedence over the requirements in this document.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

Sterile hypodermic syringes for single use —

Part 3:
Auto-disabled syringes for fixed-dose immunization

1 Scope

This document specifies the properties and performance of sterile single-use hypodermic syringes with an auto-disable syringe feature intended to deliver a fixed dose of vaccine immediately after filling. The syringes can be made of plastic, rubber or other materials and can be with or without needle and needle protection feature.

This document does not specify the design of the auto-disable syringe feature.

This document is not applicable to syringes for use with insulin (covered by ISO 8537), syringes for use with power-driven syringe pumps (covered by ISO 7886-2), reuse prevention syringes (covered by ISO 7886-4) or syringes designed to be prefilled (covered by the ISO 11040 series). It does not address compatibility with injection fluids/vaccines.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 7864:2016, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8537:2016, *Sterile single-use syringes, with or without needle, for insulin*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

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 and ISO 8537 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
auto-disable syringe feature
feature that passively activates upon delivering injection of the nominal fixed dose to prevent subsequent reuse of the syringe and the needle

Note 1 to entry: A passive activation is an activation of the reuse prevention feature that does not require an additional step by the user, separate from any action needed to perform the primary intended injection function of the device.

Note 2 to entry: An active activation is an activation of the reuse prevention feature that does require an additional step by the user.

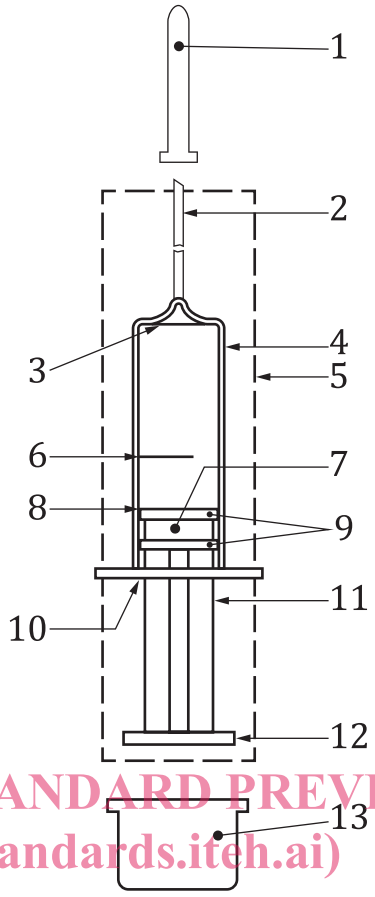
3.2
integrated needle
stainless steel cannula directly bonded into the barrel of the syringe

3.3
non-integrated needle
hypodermic needle attached either by the manufacturer or by the user prior to making an injection

3.4
normal conditions of use
operation of the device by any user according to its instructions for use

4 Nomenclature

The nomenclature for components of auto-disable syringes for fixed dose is shown in Figure 1.



Key

1	needle cap or shield (if used)	8	fiducial line
2	needle	9	seal(s)
3	zero line	10	barrel flanges (finger grips)
4	barrel	11	plunger
5	auto-disable syringe feature	12	push-button
6	nominal capacity line	13	plunger cap (if used)
7	plunger stopper		

NOTE The figure is intended to illustrate the components of an auto-disabled syringe only.

Figure 1 — Schematic representation of auto-disabled syringe for fixed dose

5 General requirements

The general requirements listed below are considered to be design input for manufacturers.

a) Syringes shall be free from defects affecting appearance, safety and serviceability for their intended use. The syringe's barrel flanges shall be of adequate size, shape and strength for the intended purpose. The design specifications for the barrel flanges shall be determined through risk analysis and confirmed through usability validation testing. The materials shall not cause the syringes to yield, under conditions of normal use, significant amounts of toxic substances and shall permit them to satisfy the appropriate requirements for freedom from pyrogenic materials and abnormal toxicity. Materials used in the construction of the wall of the syringe barrel shall have sufficient clarity to enable dosages to be read without difficulty. This document does not specify materials to be used for the construction and lubrication of the device, because their selection will

depend, to some extent, upon the manufacturer's specific syringe design, process of manufacture and sterilization method.

b) Syringes with integrated or add-on sharps protection shall conform with ISO 23908.

c) The length of the barrel shall allow the expulsion of any air bubbles without removal of the plunger stopper and still inject nominal capacity. The length of the barrel shall be designed to enable accurate dosage while avoiding unnecessary waste of vaccine.

d) Biocompatibility of the syringe shall be established in accordance with ISO 10993-1.

e) The auto-disabled syringe shall be of adequate size, shape and strength for the delivery of vaccine under normal condition of use. The design specifications for the device shall be determined through risk analysis and confirmed through usability validation testing.

f) The forces required to use a syringe with auto-disable syringe feature shall be appropriate for the intended users of the device. Although the activation of the auto-disable syringe feature itself is passive, an appropriate force shall be selected that eases the initiation of the injection. The appropriate initiation force shall be determined using a risk-based approach in accordance with ISO 14971.

6 Extraneous matter

6.1 General

The requirements specified in ISO 7886-1:2017, 6.1, apply.

6.2 Limits for acidity or alkalinity

The requirements specified in ISO 7886-1:2017, 6.2, apply except that the extracts shall be prepared in accordance with Annex A of this document.

6.3 Limits for extractable metals

The requirements specified in ISO 7886-1:2017, 6.3, apply.

7 Lubricant

The requirements specified in ISO 7886-1:2017, Clause 7 and ISO 7864:2016, 4.10.4, apply.

8 Tolerance on nominal capacity

The volume of water at (23 ± 5) °C expelled from the syringe when the fiducial line of the piston traverses the full scale (i.e. the nominal fixed dose) shall be within the tolerances on the nominal capacity as specified in Table 1. The nominal capacity shall be designated in millilitres.

Table 1 — Nominal capacity and dead space

Nominal capacity ml	Tolerance on nominal capacity %	Maximum dead space for integrated needle ml	Maximum dead space for non-integrated needle ml	Maximum displacement of position of scale %	Minimal graduation length between the fiducial line and fixed dose mm
0,05 ml up to 0,2 ml	±20 %	0,02	0,025	±20 %	2
> 0,2 ml up to 0,5 ml	±5 %	0,07	0,07	±5 %	5
> 0,5 ml up to 1,0 ml	±5 %	0,07	0,07	±5 %	10

9 Graduated scale

9.1 Scale

The scale shall have two markings only: the zero line and the nominal capacity line (i.e. the total graduated capacity line). These lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.

9.2 Position of scale

When the plunger stopper is fully inserted, the zero line of the scale shall coincide with the fiducial line on the plunger stopper in order to achieve the graduated capacity tolerance as specified in Table 1.

10 Barrel

10.1 Dimensions

The length of the barrel and the design of the auto-disable syringe feature shall be such that the maximum usable capacity shall not exceed the nominal capacity by more than 25 %.

10.2 Barrel flanges

The requirements specified in ISO 7886-1:2017, 10.2, apply.

11 Plunger stopper/plunger assembly

11.1 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. The plunger stopper shall not become detached from the plunger when tested in accordance with ISO 8537:2016, Annex B, for a syringe with integrated needle or in accordance with ISO 7886-1:2017, Annex B for a syringe without needle.

The plunger should be of a length adequate to allow the piston to properly deliver the nominal fixed dose. It should not be possible to defeat the auto-disable syringe feature by removing and re-inserting the plunger.

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 fiducial line of the plunger stopper coincides with