SLOVENSKI STANDARD
oSIST prEN ISO 7886-3:2017

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Sterilne podkožne injekcijske brizge za enkratno uporabo - 3. del: Brizge za točno določen odmerek imunizacije s sistemom za samouničenje (ISO/DIS 7886-3:2016)

Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization (ISO/DIS 7886-3:2016)

Sterile Einmalspritzen für medizinische Zwecke - Teil 3: Selbstblockierende Spritzen für die Injektion mit fixer Impfstoffdosis (ISO/DIS 7886-3:2016)

Seringues hypodermiques stériles, non réutilisables - Partie 3: Seringues autobloquantes pour vaccination à dose fixe (ISO/DIS 7886-3:2016)

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11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

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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

ICS: 11.040.25

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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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

ISO 7886-3 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

In some countries national regulations are legally binding and the requirements may take precedence over this International Standard.

This second edition cancels and replaces ISO 7886-3:2005, which has been technically revised.

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-disabled syringes for fixed-dose immunization*

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

The main changes to the previous edition of ISO 7886-3 introduced by this revision are:

Change in scope of the standard: Upon commencement of injection of a nominal fixed dose of vaccine, the auto-disable feature of the syringe is passively activated so that the syringe cannot be reused.

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 third part of ISO 7886 was recognized as a high priority requirement to prevent the re- use of fixed dose immunization 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.

The World Health Organization had produced a specification for syringes that are rendered inactive after one use (commonly referred to as "auto-disabled" syringes). Both the WHO and ISO agreed that an additional part of ISO 7886 would be required to cover "auto-disabled" syringes, whilst leaving in place ISO 7886 Parts 1 and 2 without modification, as a large number of devices in common use would not be intended to comply with the auto-disable properties suggested.

This part of ISO 7886 is intended to cover "fixed dose" immunization syringes that are passively rendered non-reusable for another application after the commencement of injection intended to deliver a nominal vaccine dose. These syringes are not covered by Parts 1 and 2 of ISO 7886.

Based on field feedback, the World Health Organization recommended to make further amendments to this standard for enhanced safety and to bring more clarification to requirements. These amendments are covered in this revision of this standard.

It is recognized that syringes designed to reduce the risk of needle stick injuries, may also comply with this part of ISO 7886 with regard to their auto-disable properties, but it is stressed that needle stick protection features of syringes are not in themselves addressed in this part of ISO 7886. Requirements for sharps injury protection features are covered by ISO 23908.

Guidance on transition periods for implementing the requirements of this standard is given in ISO/TR 19244 'Guidance on transition periods for standards developed by ISO/TC 84 - Devices for administration of medicinal products and catheters'.

Sterile hypodermic syringes for single use —

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

1 Scope

This part of ISO 7886 specifies the properties and performance of sterile single-use hypodermic syringes with or without needle, made of plastic or other materials and intended for the filling and the injection of vaccines immediately after filling. Upon commencement of injection of a nominal fixed dose of vaccine, the auto-disable feature of the syringe is passively activated so that the syringe cannot be reused.

This part of ISO 7886 does not specify the design of the auto-disable feature, which is left to the discretion of the manufacturer.

This part of ISO 7886 is not applicable to syringes for use with insulin (specified in ISO 8537), syringes for use with power-driven syringe pumps (specified in ISO 7886-2), reuse prevention syringes (specified in ISO 7886-4) and syringes designed to be prefilled. It does not address compatibility with injection fluids/vaccines.

NOTE Prefilled syringes are covered under ISO 11040- series.

2 Normative references

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

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2:1998, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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 8537:2016, *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 14971, *Medical devices — Application of risk management to medical devices*

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

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*

ASTM D999-08, *Standard methods for vibration testing of shipping containers*

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

NOTE ISO 594-1:1986 and ISO 594-2:1998 will be replaced by ISO 80369-7.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7886-1 (except 3.2) and ISO 8537 (except 3.5) and the following apply.

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

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

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

3.1
auto-disabled syringe feature
feature that passively activates upon commencement of injection of the nominal fixed dose to prevent subsequent re-use of the syringe and the needle

3.2
passive activation
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

3.3
active activation
activation of the reuse prevention feature that does require an additional step by the user

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

3.5
integrated needle
stainless steel cannula that is directly bonded into the barrel of the syringe

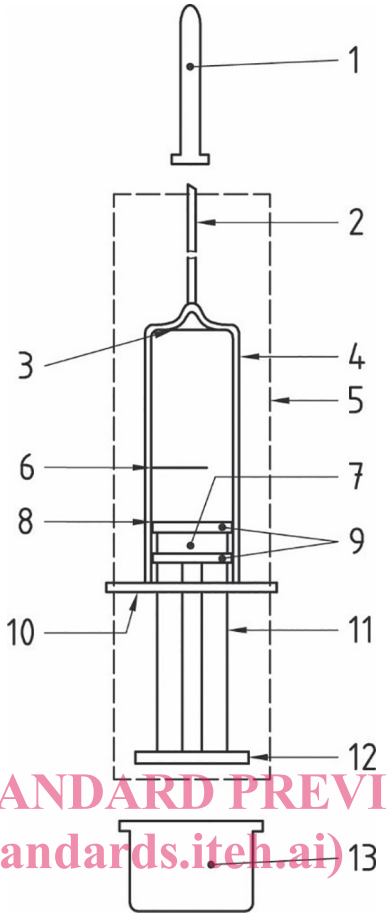
3.6
non-integrated needle
hypodermic needle assembly that is fixed or bonded by the manufacturer to the barrel, or a hypodermic needle that is attached by the user prior to making an injection

3.7
barrel flanges
flanges that protrude from the barrel (also referred to as finger grips) to provide the user a means of gripping the syringe during injection

3.8
needle cap or shield
sheath intended to physically protect the needle prior to use

4 Nomenclature

The nomenclature for components of auto-disabled 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 feature	12	push-button
6	nominal capacity line	13	plunger cap (if used)
7	plunger stopper		

NOTE The drawing is intended to be illustrative of components of an auto-disabled syringe only.

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

5 Requirements

5.1 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 national requirements or regulations for freedom from pyrogenic