SLOVENSKI STANDARD
oSIST prEN ISO 7886-4:2018

01-januar-2018

Sterilne podkožne injekcijske brizge za enkratno uporabo - 4. del: Injekcije, katerih značilnosti preprečujejo ponovno uporabo (ISO/DIS 7886-4:2017)

Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature (ISO/DIS 7886-4:2017)

Sterile Injektionskanülen für den Einmalgebrauch - Teil 4: Spritzen mit Vorrichtung zur Verhinderung der Wiederverwendung (ISO/DIS 7886-4:2017)

Seringues hypodermiques stériles, non réutilisables - Partie 4: Seringues avec dispositif empêchant la réutilisation (ISO/DIS 7886-4:2017)

Ta slovenski standard je istoveten z: **prEN ISO 7886-4**

ICS:

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

oSIST prEN ISO 7886-4:2018 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 7886-4

ISO/TC **84** Secretariat: **DS**

Voting begins on: **2017-10-20**

Voting terminates on: **2018-01-12**

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

ICS: 11.040.25

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 7886-4:2017(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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.

The committee responsible for this document is Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition (ISO 7886-4:2006), which has been technically revised.

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

Introduction

The preparation of this document was recognized as a high priority requirement to prevent intentional (misuse) or accidental reuse of syringes. Re-use of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens. See Reference [2] 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” (AD) syringes) for both fixed dose immunization and syringes with re-use prevention features for general/curative purposes and the reconstitution of vaccines. For the purpose of this document, auto disabled is used for the feature of type 1 re-use prevention which operates automatically during or upon completion of the intended single use. 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 document is intended to cover syringes that are rendered inoperable, either during or upon completion or 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 needle-stick injuries can also comply with this document with regard to their re-use prevention properties, but it is stressed that anti-needle-stick properties of syringes are not in themselves addressed in this document.

Sterile hypodermic syringes for single use —

Part 4: Syringes with re-use prevention feature

1 Scope

This document specifies requirements for sterile single-use hypodermic syringes made of plastic and rubber 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 document is not applicable to syringes made of glass (specified in ISO 595 (withdrawn)), 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 document.

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

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

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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 7886-3, *Sterile hypodermic syringes for single use — Part 3: Auto-disabled syringes for fixed-dose immunization*[1)]

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*

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.

1) Revision is in preparation (ISO/DIS stage)

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

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

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

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

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

[SOURCE: ISO 7886-3, 3.2]

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

[SOURCE: ISO 7886-3, 3.3]

3.4
auto disable feature
feature that automatically activates, prior to end of injection, to render the syringe unusable by the delivery of the intended dosage

4 Types of syringe

4.1 General

Syringe types shall be categorized in accordance with 4.2 and 4.3.

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.

4.2 Types of re-use prevention feature

The re-use prevention feature shall be either:

— Type 1: (auto-disabled feature);

— Type 2: feature that requires elective activation upon completion of intended single use (i.e. active activation).

4.3 Types of intended use/application

The intended use/application shall be one of the following:

— Type A: design that allows for only a single aspiration and injection;

— Type B: design that allows for multiple plunger aspirations prior to the final intended single use.

