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

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 7886-3:2020 sisaldab Euroopa standardi EN ISO 7886-3:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 7886-3:2020 consists of the English text of the European standard EN ISO 7886-3:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 20.05.2020.	Date of Availability of the European standard is 20.05.2020.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 7886-3

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English Version

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

Seringues hypodermiques stériles, non réutilisables - Partie 3: Seringues autobloquantes pour vaccination à dose fixe (ISO 7886-3:2020)

Sterile Einmalspritzen für medizinische Zwecke - Teil 3: Selbstblockierende Spritzen für die Injektion mit fixer Impfstoffdosis (ISO 7886-3:2020)

This European Standard was approved by CEN on 24 April 2020.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 7886-3:2020) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2020, and conflicting national standards shall be withdrawn at the latest by November 2020.

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

This document supersedes EN ISO 7886-3:2009.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 7886-3:2020 has been approved by CEN as EN ISO 7886-3:2020 without any modification.

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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).

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

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.