SLOVENSKI STANDARD
SIST EN ISO 7886-4:2019

01-maj-2019

Nadomešča:
SIST EN ISO 7886-4:2010

Sterilne podkožne injekcijske brizge za enkratno uporabo - 4. del: Injekcije, katerih značilnosti preprečujejo ponovno uporabo (ISO 7886-4:2018)

Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature (ISO 7886-4:2018)

Sterile Injektionskanülen für den Einmalgebrauch - Teil 4: Spritzen mit Vorrichtung zur Verhinderung der Wiederverwendung (ISO 7886-4:2018)

Seringues hypodermiques stériles, non réutilisables - Partie 4: Seringues avec dispositif empêchant la réutilisation (ISO 7886-4:2018)

Ta slovenski standard je istoveten z: **EN ISO 7886-4:2019**

ICS:

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

SIST EN ISO 7886-4:2019 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 7886-4

March 2019

ICS 11.040.25

Supersedes EN ISO 7886-4:2009

English Version

Sterile hypodermic syringes for single use - Part 4: Syringes with re-use prevention feature (ISO 7886-4:2018)

Seringues hypodermiques stériles, non réutilisables - Partie 4: Seringues avec dispositif empêchant la réutilisation (ISO 7886-4:2018)

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This European Standard was approved by CEN on 1 March 2019.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

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Ref. No. EN ISO 7886-4:2019 E

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European foreword

This document (EN ISO 7886-4:2019) 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of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.

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 7886-4:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZA, which is an integral part of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 7886-4:2018 has been approved by CEN as EN ISO 7886-4:2019 without any modification.

INTERNATIONAL STANDARD

ISO 7886-4

Second edition
2018-11

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.

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*.

This second edition cancels and replaces the first edition (ISO 7886-4:2006), which has been technically revised. The main changes compared to the previous edition are as follows:

— terminology in Introduction is clarified;

— general reference update (Normative references, Bibliography and main body of the text);

— definitions for "active activation" and "auto-disable feature" added;

— test of syringes: Harmonized definitions with ISO 7886-3 and clarified text;

— Figure 1 is removed and substituted with a reference to the figure in ISO 7886-1;

— barrel dimension – the additional 20 % capacity is removed;

— dimensions in design section are clarified;

— alignment with ISO 7886-1 and ISO 7886-3;

— subclause 15.5, Guidance on material, has been removed;

— Figure 3 (safety box) is removed;

— Annex C is deleted.

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.