SLOVENSKI STANDARD
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Sterilne podkožne injekcijske brizge za enkratno uporabo - 1. del: Injekcijske brizge za ročno injiciranje (ISO/DIS 7886-1:2015)

Sterile hypodermic syringes for single use - Part 1: Syringes for manual use (ISO/DIS 7886-1:2015)

Sterile Einmalspritzen für medizinische Zwecke - Teil 1: Spritzen zum manuellen Gebrauch (ISO/DIS 7886-1:2015)

Seringues hypodermiques stériles, non réutilisables - Partie 1: Seringues pour utilisation manuelle (ISO/DIS 7886-1:2015)

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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 1: Syringes for manual use

Seringues hypodermiques stériles, non réutilisables —

Partie 1: Seringues pour utilisation manuelle

ICS: 11.040.25

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 7886-1 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 the first edition (ISO 7886-1:1993), 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 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 7886-1 introduced by this revision are:

a) Clarified the scope e.g. excluding single-use syringes made of glass

b) Added some Normative references

c) Added new definitions

d) Clarified the drawing to illustrate the component of the syringe

e) Included general requirements

f) Revised test methods for syringes

g) Revised the labelling requirement

h) Clarified the type of lubricant for the different types of syringes

i) Added a new Annex G (informative) Test method for the quantity of silicone

j) Informative annex on materials has been deleted.

Introduction

This International Standard covers hypodermic syringes primarily intended for human use and provides performance and testing requirements. It permits broader variation in design so as to not limit innovation and methods of packaging. Its appearance and layout are consistent with other TC 84 standards which are designed to be more performance-based compared to design prescriptive.

General requirements as design guidelines for manufacturers are introduced in the edition. A number of limits for requirements which is historic based but confirmed in practice for many years, have been kept.

Materials to be used for the construction and lubrication of sterile syringes for single use are not specified as their selection will depend to some extent upon the design, process of manufacture and sterilization method employed by individual manufacturers. The materials of the syringe should be compatible with injection fluids. If this is not the case, the attention of the user should be drawn to the exception by labelling unit packaging. It is practicable to specify a universally acceptable test method for incompatibility. However, recommended methods are given in Annex E. These test methods can be regarded only as means of indicating compatibility. The only conclusive test is that of an individual injection fluid with a specific syringe.

Manufacturers of pharmaceuticals use solvents in injectable preparations. Such solvents should be tested by the manufacturer of the injectable preparation for any possible incompatibility with the materials frequently used in syringe construction. If an incompatibility is identified, the injection fluid should be suitably labelled. The impossibility of testing any one injection fluid with all available syringes is recognized and it is strongly recommended that regulatory authorities and relevant trade associations should recognize the problem and take appropriate measure to assist manufacturers.

Syringes should be manufactured and sterilized in accordance with recognized national or international codes of good manufacturing practice for medical devices.

The sampling plans for inspection selected for this standard are intended to verify the design at a high confidence level. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality systems, for example the ISO 9000 series and ISO 13485.

Manufacturers are expected to follow a risk-based approach and employ usability engineering during the design, development and manufacture of syringes.

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 1: Syringes for manual use

1 Scope

This part of ISO 7886 specifies requirements and test methods for verifying the design of empty sterile single-use hypodermic syringes, made of plastic materials and intended for the aspiration and injection of fluids after filling by the end-users. This standard does not provide requirements for lot release. The syringes are primarily for use in humans.

Sterile syringes specified in this International Standard are intended for use immediately after filling as they are not suitable for containing fluids over extended periods of time.

It excludes syringes for use with insulin (see ISO 8537), single-use syringes made of glass, syringes for use with power-driven syringe pumps, syringes pre-filled by the manufacturer, and syringes intended to be stored after filling (e.g. in a kit for filling by a pharmacist).

Hypodermic syringes without a needle specified in this part of ISO 7886 are intended for use with hypodermic needles specified in ISO 7864.

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

ISO 15223-1, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*

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*

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 following terms and definitions apply.

3.1
nominal capacity
capacity of the syringe as designated by the manufacturer

NOTE 1 to entry: Examples are 1 ml, 5 ml, 50 ml.

3.2
graduated capacity
volume of water at 18 °C to 28 °C expelled from the syringe when the fiducial line on the piston traverses a given scale interval or intervals

3.3
total graduated capacity
capacity of the syringe at the graduation line furthest from the zero graduation line

NOTE 1 to entry: The total graduated capacity may be equal to, or greater than, the nominal capacity.

3.4
maximum usable capacity
capacity of the syringe when the piston is drawn back to its furthest functional position

3.5
fiducial line
leading edge on the plunger stopper, which is in contact with and perpendicular to the syringe barrel and aligns with the zero marking on the syringe barrel when the piston is fully inserted

3.6
unit packaging
packaging which has the direct contact with the device and maintains the sterility of the product

3.7
user packaging
packaging designed to contain one or more unit packages or self-contained syringe units

Note 1 to entry: Self-contained syringe units can be packed in multiple unit packs

3.8
two-piece syringe
syringe assembly comprises of the barrel, plunger and plunger stopper, whereas plunger and plunger stopper form one component made of the same material, that contains a slip additive to allow smooth plunger movement

3.9
three-piece syringe
syringe assembly includes the barrel, plunger and plunger stopper, whereas plunger and plunger stopper are two separate components of different material

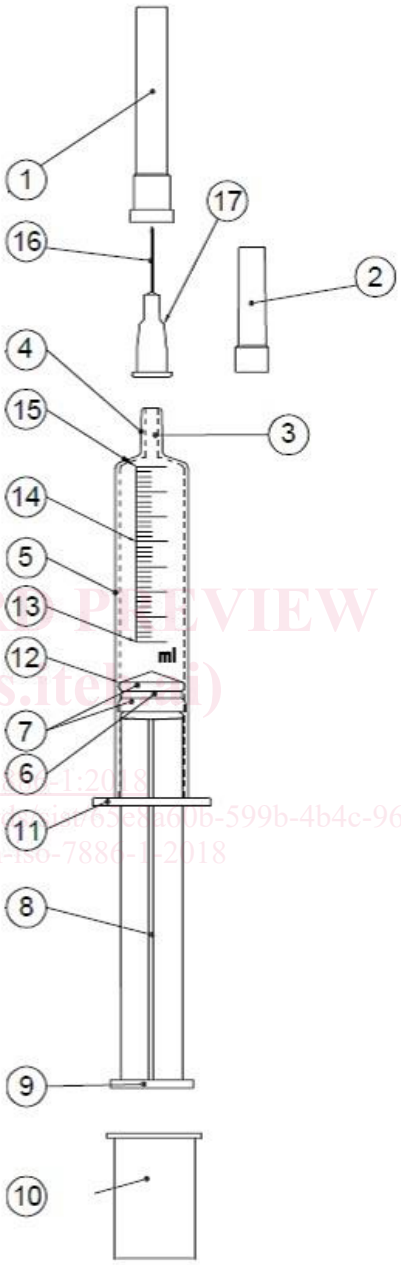
3.10
nozzle cap
sheath intended to protect physically the needle hub prior to use

3.11
plunger stoppers
component which seals one end of the syringes and interfaces with the plunger

3.13
self-contained syringe
syringe with protective end caps (i.e., plunger cap, and nozzle cap or needle cap) intended to maintain the sterility of the interior of the syringe

4 Nomenclature

The nomenclature for components of hypodermic syringes for single use is shown in Figure 1.



Key

1	needle cap	10	plunger cap
2	nozzle cap	11	finger grips
3	nozzle lumen	12	fiducial line
4	nozzle	13	nominal capacity
5	barrel	14	graduation lines
6	plunger stopper (3 Piece only)	15	zero line