INTERNATIONAL STANDARD

ISO 7886-1

Second edition
2017-05

Corrected version
2019-08

Sterile hypodermic syringes for single use —

Part 1: Syringes for manual use

Seringues hypodermiques stériles, non réutilisables —

Partie 1: Seringues pour utilisation manuelle

Reference number
ISO 7886-1:2017(E)

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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 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 the following URL: 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 7886-1:1993), which has been technically revised. It also incorporates the Technical corrigendum ISO 7886-1:1993/Cor.1:1995.

The main changes to the previous edition are the following:

a) clarified the Scope, e.g. excluding single-use syringes made of glass;

b) added new Normative references;

c) added new terms and 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) replaced Annex E (informative): Examples of test methods for incompatibility between syringes and injection fluids with Annex E (informative): Test method for the determination of forces required to operate the piston;

j) added Annex F (informative): Test method for the quantity of silicone;

k) informative annex on materials has been deleted.

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

This corrected version of ISO 7886-1:2017 incorporates the following corrections:

— In the key to Figure E.1, item 2 was corrected to read "needle [1,2 mm (18 G) and approximately 40 mm length";

— In the key to Figure E.1, item 3 was corrected to read " tubing [(2,7 ± 0,1) mm i.d. and (500 ± 5) mm in length with male and female Luer adapters at each end)]";

— In E.2.3, the value "(19,5 ± 0,5) cm" was changed to "(500 ± 5) mm".

Introduction

The ISO 7886 series covers hypodermic syringes primarily intended for human use and provides performance and testing requirements. It permits broader variation in design so as not to limit innovation and methods of packaging. Its appearance and layout are consistent with other related standards which are designed to be more performance-based compared to design prescriptive.

General requirements as design guidelines for manufacturers are introduced in this document. Several limits for requirements which are 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 on unit packaging. It is not practicable to specify a universally acceptable test method for incompatibility, as the only conclusive test is that an individual specific injection fluid is compatible 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 measures to assist manufacturers of injectable preparations.

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 the ISO 7886 series 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 requirements 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 ISO 7886 (all parts) is given in ISO/TR 19244.

Sterile hypodermic syringes for single use —

Part 1:
Syringes for manual use

1 Scope

This document specifies requirements and test methods for verifying the design of empty sterile single-use hypodermic syringes, with or without needle, made of plastic or other materials and intended for the aspiration and injection of fluids after filling by the end-users. This document does not provide requirements for lot release. The syringes are primarily for use in humans.

Sterile syringes specified in this document are intended for use immediately after filling and are not intended to contain the medicament for 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 document are intended for use with hypodermic needles specified in ISO 7864.

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 15223-1:2016, *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*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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
nominal capacity
capacity of the syringe as designated by the manufacturer

EXAMPLE 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

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 that 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 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 the barrel and piston, whereas plunger and plunger stopper form one component made of the same material

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

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

3.11
plunger stopper
component connected to the leading end of the plunger and seals the open end of the syringe barrel

3.12
self-contained syringe
syringe with protective end caps [i.e. plunger cap, and nozzle cap or *needle cap* (3.17)] intended to maintain the sterility of the interior of the syringe

3.13
dead space
residual volume of fluid left in syringe when the *plunger stopper* (3.11) is fully depressed

3.14
multiple unit pack
multiple syringes packaged with a single seal that maintains the sterility of the product

3.15
piston
assembled component of plunger and *plunger stopper* (3.11)

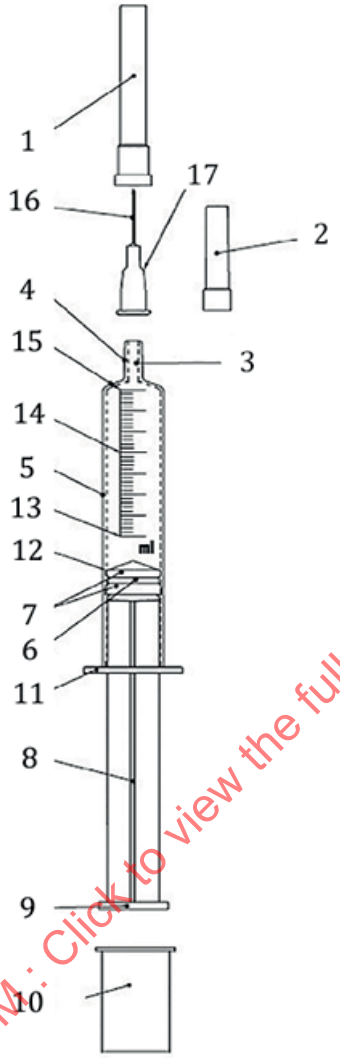
3.16
barrel flanges
flanges that protrude from the barrel (also referred to as finger grips) to provide the user an ergonomic means of gripping the syringe during injection

3.17
needle cap or shield
sheath intended to physically protect the needle prior to use

3.18
plunger
device component which advances the *plunger stopper* (3.11) to deliver the medicinal product

4 Nomenclature

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



Key

1 needle cap or shield (if used)
2 nozzle cap
3 nozzle lumen
4 nozzle
5 barrel
6 plunger stopper (3-piece only)
7 seals
8 plunger
9 push-button
10 plunger cap
11 barrel flanges (finger grips)
12 fiducial line
13 nominal capacity
14 graduation lines
15 zero line
16 needle tube
17 hub

NOTE The figure is intended to be illustrative of the components of a syringe. The plunger stopper/plunger assembly can or cannot be of integral construction and can or cannot incorporate more than one seal.

Figure 1 — Schematic representation of hypodermic syringe for single use

5 General requirements

The general requirements are considered to be design inputs for manufacturers.

a) Syringes shall be free from defects affecting appearance, safety and performance for their intended use. Syringes with integrated or add-on sharps protection shall comply with ISO 23908.

   — 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 materials and abnormal toxicity.

   — Materials used in the construction of the wall of the syringe barrel shall have sufficient clarity to enable dosages to be read without difficulty.

   — The standard does not specify materials to be used for the construction and lubrication of sterile syringes with or without needles for single use, because their selection will depend, to some extent, upon the manufacturers specific syringe design, process of manufacture and sterilization method.

b) The design and validation of the packaging shall take into consideration the final use of the syringe and the storage and shipping conditions and the defined shelf life.

6 Extraneous matter

6.1 General

The surfaces of the syringe that come in contact with injection fluids during normal use shall be free from particles and extraneous matter.

NOTE Compliance with this requirement will be determined through inspection by an individual with normal vision (or corrected-to-normal vision), without magnification.

6.2 Limits for acidity or alkalinity

Exposure of distilled water to the finished syringe product shall not change its pH value by more than one unit.

Compliance with this requirement shall be demonstrated by preparing the solutions described in Annex A. The results shall show that the pH value of the syringe assessment fluid is within one pH unit of the pH value of the control fluid.

The pH value of both solutions may be determined with a laboratory potentiometric pH meter using a general purpose electrode.

6.3 Limits for extractable metals

Exposure of distilled water to the finished syringe product shall not change its content of metals by more than a combined total of 5 mg/kg of lead, tin, zinc and iron; the cadmium content shall be less than 0,1 mg/kg.

Compliance with this requirement shall be demonstrated by preparing the solutions described in Annex A and testing them using a recognized micro-analytical method, for example, by an atomic absorption method or by an inductively coupled plasma mass spectrometry method (ICP).

7 Lubricant

When the plunger stopper is fully inserted the amount of lubricant applied into the barrel shall not reach the Luer channel of the nozzle.

For lubricants applied to interior surface of the syringe, the quantity of lubricant applied shall not exceed 0,25 mg/cm^2 of the interior surface area of the syringe in contact with the injection fluid.

The amount and distribution of lubricant applied should be optimized to minimize lubricant visibility.

NOTE 1 An acceptable lubricant is silicone complying with a national or the European pharmacopoeia and ISO 10993-1.

For lubricants incorporated in the polymer formulation, the quantity of lubricant shall not exceed 0,6 % (w/w) of the mass of the component, but attention is drawn to the fact that some national regulations may specify a lower maximum concentration.

NOTE 2 If a lubricant is incorporated in the polymer formulation, visible particles can become apparent when the lubricant blooms to the surface of the syringe barrel and the plunger stopper scrapes it off.

NOTE 3 Example of acceptable lubricants incorporated in the polymer formulation are fatty acid amides of erucic and/or oleic acids complying with ISO 10993-1.

NOTE 4 See Annex F for a test method for the quantity of silicone oil.

8 Tolerance on graduated capacity

The tolerances on the graduated capacity shall be as given in Table 1.

Table 1 — Capacity tolerance, dead space, scale dimensions and test forces

Nominal capacity of syringe V ml	Tolerance on any graduated capacity		Maximum dead space ml	Minimum overall length of scale to nominal capacity mark mm	Scale interval ml	Increment between graduation lines to be numbered ml	Forces for leakage testing (see Annex D)	
	Less than half nominal capacity	Equal to or greater than half nominal capacity					Side force (±5 %) N	Axial pressure (gauge) (±5 %) kPa
$V < 2$	±(1,5 % of V + 2 % of expelled volume)	±5 % of expelled volume	0,07	57	0,05	0,1	0,25	300
$2 \leq V < 5$	±(1,5 % of V + 2 % of expelled volume)	±5 % of expelled volume	0,07	27	0,2	1	1,0	300
$5 \leq V < 10$	±(1,5 % of V + 1 % of expelled volume)	±4 % of expelled volume	0,075	36	0,5	1	2,0	300
$10 \leq V < 20$	±(1,5 % of V + 1 % of expelled volume)	±4 % of expelled volume	0,10	44	1,0	5	2,0	300

NOTE Expelled volume means all the liquid ejected with the seal brought to the physical limit that was designed to be coincident with the zero mark of the scale.

EXAMPLE 1 For a 3 ml syringe, when filled to the 1 ml graduation (less than 1/2 capacity), the required tolerance would be ±(1,5 % × 3 ml + 2 % × 1 ml) = 0,065 ml

EXAMPLE 2 For a 3 ml syringe, when filled to the 2 ml graduation (greater than 1/2 capacity), the required tolerance would be ±(5 % × 2 ml) = 0,100 ml.

Table 1 *(continued)*

Nominal capacity of syringe V ml	Tolerance on any graduated capacity		Maximum dead space ml	Minimum overall length of scale to nominal capacity mark mm	Scale interval ml	Increment between graduation lines to be numbered ml	Forces for leakage testing (see Annex D)	
	Less than half nominal capacity	Equal to or greater than half nominal capacity					Side force (±5 %) N	Axial pressure (gauge) (±5 %) kPa
$20 \leq V < 30$	±(1,5 % of V + 1 % of expelled volume)	±4 % of expelled volume	0,15	52	2,0	10	3,0	200
$30 \leq V < 50$	±(1,5 % of V + 1 % of expelled volume)	±4 % of expelled volume	0,17	67	2,0	10	3,0	200
$V \geq 50$	±(1,5 % of V + 1 % of expelled volume)	±4 % of expelled volume	0,20	75	5,0	10	3,0	200

NOTE Expelled volume means all the liquid ejected with the seal brought to the physical limit that was designed to be coincident with the zero mark of the scale.

EXAMPLE 1 For a 3 ml syringe, when filled to the 1 ml graduation (less than 1/2 capacity), the required tolerance would be ±(1,5 % × 3 ml + 2 % × 1 ml) = 0,065 ml

EXAMPLE 2 For a 3 ml syringe, when filled to the 2 ml graduation (greater than 1/2 capacity), the required tolerance would be ±(5 % × 2 ml) = 0,100 ml.

9 Graduated scale

9.1 Scale

9.1.1 The syringe shall have either only one scale or more than one identical scales, which shall be graduated and numbered at least at the intervals given in Table 1. The unit of volume shall be marked on the barrel.

NOTE The scale interval can be less (finer) than the scale interval given in Table 1.

If necessary by a specific application, the scale may vary and this requirement does not preclude the provision of additional graduation marks within the scale or as extensions to the scale. Any variation of the scale or graduation is recommended to be assessed for risk according to ISO 14971 and for usability according to IEC 62366.

9.1.2 The total graduated capacity may be equal to, or greater than, the nominal capacity. If the scale is extended beyond the nominal capacity, the extended portion shall be differentiated from the rest of the scale.

Examples of means of differentiation are the following:

a) encircling the scale number of the nominal capacity line;

b) using smaller scale numbers for the extra graduation lines;

c) using shorter graduation lines for the extra graduation lines;

d) using a broken line for the optional vertical line of the extra scale length.

9.1.3 Graduation lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.

9.1.4 Graduation lines shall be evenly spaced along the longitudinal axis between the zero graduation line and the line for the total graduated capacity.

9.1.5 When the syringe is held vertically, the ends of all graduation lines of similar length shall be vertically beneath each other.

The lengths of the short graduation lines on each scale are recommended to be approximately half the length of the long lines. If different graduation line configurations are used, this could be submitted to usability evaluation according to IEC 62366.

Examples of scales and the numbering of graduation lines are shown in Figure 2.

NOTE 1 The vertical line of the scale may be omitted.

NOTE 2 The figure is not to scale.

Figure 2 — Examples of scale graduations

9.2 Numbering of scales

9.2.1 Graduation lines shall be numbered at least at the volume increments given in Table 1. In addition, the line denoting the nominal capacity or the lines denoting the nominal capacity and the total graduated capacity, if these differ, shall be numbered.

Examples of scale numbering are shown in Figure 2.

9.2.2 When the syringe is held vertically with the conical tip uppermost and with the scale to the front, the numbers shall appear vertical on the scale and be approximately centred on the graduation lines to which they relate. The numbers shall be close to, but shall not touch, the ends of the graduation lines to which they relate.

9.3 Overall length of scale to nominal capacity line

The overall length of the scale shall be as given in Table 1.

9.4 Position of scale

When the plunger stopper is fully inserted, the zero graduation line of the scale shall coincide with the fiducial line on the plunger stopper in order to achieve the graduated capacity tolerance as stated in Table 1.

10 Barrel

10.1 Dimensions

Maximum capacity shall be determined by risk assessment with consideration of, for example, removal of air bubbles or risk of overdose.

10.2 Barrel flanges

The open end of the barrel shall be provided with barrel flanges. Barrel flanges shall be of adequate size, shape and strength for the intended purpose and shall enable the syringe to be held securely during use. The syringe design, such as barrel flanges, shall be such that the syringe will not roll more than 180° when it is placed on a flat surface at an angle of 10° to the horizontal. The barrel flanges shall be free from flash and sharp edges.

Finger grip configurations that do not conform to these requirements are recommended to be assessed for risk according to ISO 14971 and for usability according to IEC 62366.

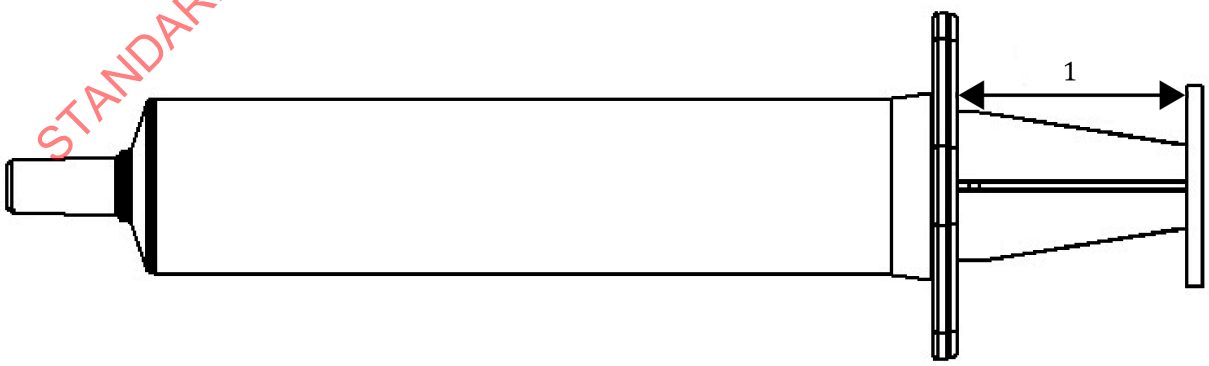
11 Plunger stopper/plunger assembly

11.1 Design

When tested in accordance with Annex B, the plunger stopper shall not become detached from the plunger.

The plunger shall be of a length adequate to allow the plunger stopper to traverse the full length of the barrel, but it shall not be possible to easily withdraw the piston completely from the barrel.

The projection of the plunger and the configuration of the push-button should be such as to allow the plunger to be operated without difficulty. When the fiducial line of the plunger stopper coincides with the zero graduation line, the minimum length of the plunger from the surface of the barrel flanges nearer to the push-button, as shown in Figure 3, shall be at least 8 mm.



Key

1 minimum 8 mm

Figure 3 — Minimum length between barrel flanges and plunger push-button

12 Nozzle

12.1 Conical fitting

The male conical fitting of the syringe nozzle shall be in accordance with ISO 80369-7.

If the syringe has a locking fitting, it shall be in accordance with ISO 80369-7.

12.2 Position of nozzle on end of barrel

12.2.1 On syringes of nominal capacity of less than 5 ml, the syringe nozzle shall be situated centrally, i.e. it shall be coaxial with the barrel.

12.2.2 On syringes of nominal capacity of 5 ml and greater, the syringe nozzle shall be situated either centrally or eccentrically.

12.2.3 If the syringe nozzle is eccentric, its axis shall be vertically below the axis of the barrel when the syringe is lying on a flat surface with the scale uppermost. The distance between the axis of the nozzle and the nearest point on the internal surface of the bore of the barrel shall be not greater than 4,5 mm.

12.3 Nozzle lumen

The nozzle lumen shall have a diameter of not less than 1,2 mm.

13 Performance

13.1 Dead space

Dead space shall be minimized to reduce waste and transmission of infectious agents.

When tested in accordance with Annex C, the maximum volume of liquid contained in the barrel and the nozzle when the plunger stopper is fully inserted shall be as given in Table 1.

13.2 Freedom from air and liquid leakage past plunger stopper

When tested in accordance with Annex D, there shall be no leakage of water past the plunger stopper or seal(s). Small droplets between the seals are not considered failure.

When tested in accordance with Annex B, there shall be no leakage of air past the plunger stopper or seal(s), and there shall be no fall in the manometer reading.

13.3 Force to operate the piston

It is recommended to measure the force to operate the piston. A suggested test method and performance criteria for the forces requirement to move the plunger stopper is given in Annex E.

13.4 Fit of plunger stopper/plunger in barrel

When the syringe is filled with water to the nominal capacity and held vertically with first one end and then the other end uppermost, the piston shall not move by reason of its own mass and the water contained.

14 Packaging

14.1 Unit packaging and self-contained syringe units

14.1.1 Unit packaging

The syringe, together with the needle if supplied, shall be sealed individually in a unit packaging.

The needle may be packaged in its own packaging inside the unit packaging.

The materials and design of the unit packaging should have no detrimental effects on the contents and shall ensure the following:

a) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;

b) minimum risk of contamination of the contents during opening and removal from the packaging;

c) adequate protection of the contents during normal handling, transit and storage;

d) that once opened, the packaging cannot be easily resealed, and it shall be obvious that the packaging has been opened.

14.1.2 Self-contained syringe units

The syringe shall be fitted with needle cap and plunger cap.

The materials and design of the syringe unit shall ensure the following:

a) maintenance of sterility of the interior of the syringe unit (e.g. the outside surface of the needle, the protruding part of the plunger and its push-button and the fluid path of the syringe, and needle, if fitted) under dry, clean and adequately ventilated conditions;

b) minimum risk of contamination of the contents during opening of the unit;

c) adequate protection of the contents during normal handling, transit and storage.

The syringe or the syringe unit may be provided with a means of indicating that the unit may have been opened previously.

14.2 Multiple unit pack

The materials and design of the multiple unit pack shall ensure the following:

a) minimum risk of contamination of the syringe unit during opening of the pack;

b) adequate protection of the syringe units during normal handling, transit and storage;

c) that once opened, it shall be obvious that the multiple pack has been opened.

14.3 User packaging

A number of unit packaging, syringe units, or a number of multiple unit packs shall be packed in a user packaging.

The packaging system shall provide physical protection and integrity of the sterile barrier system during normal handling, transit, and storage over the shelf life, i.e. until the expiration date.

15 Information supplied by the manufacturer

15.1 General

The syringe shall be accompanied by the information that is sufficient for its safe use, taking account of the training and knowledge of potential users. The information shall include the identity of the manufacturer.

15.2 Syringes

15.2.1 General

The barrels of syringes shall be marked with the following information:

a) appropriate graduated scale in accordance with Clauses 8 and 9;

b) total graduated capacity in millilitres.

15.2.2 Additional marking for self-contained syringe units

The syringe or unit shall additionally be marked with the following information:

a) the words "For single use" or equivalent, such as the symbol for "Do not re-use" (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term "disposable" shall not be used;

b) name and/or registered trademark of the manufacturer and, where applicable, reference to its authorized representative.

A warning to check the integrity of the seals of the self-contained syringe unit before use may be given.

All information appearing on the barrel should be marked in such a position as to interfere as little as possible with the reading of the graduated scale.

15.3 Unit packaging

The unit packaging shall be marked with the following information:

a) the word "STERILE" or equivalent, such as the symbol for "Sterile" (see ISO 15223-1:2016, Table 1, symbol number 5.2.1);

b) the words "For single use" or equivalent, such as the symbol for "Do not re-use" (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term "disposable" shall not be used;

c) an identification reference to the batch code or lot number, prefixed by the symbol "Batch code" (see ISO 15223-1:2016, Table 1, symbol number 5.1.5), or the word "LOT";

d) the external diameter and length of the needle in millimetres, if included; the gauge size of the needle may also be marked.

A warning to check the integrity of the unit packaging before use may be given; such as using the symbol for "Do not use if package is damaged". See ISO 15223-1:2016, Table 1, symbol number 5.2.8.

Symbols that indicate the sterilization method may also be used. See ISO 15223-1:2016, Table 1, symbol numbers 5.2.2 to 5.2.5.

The unit packaging shall also be marked with the following information unless the product bears the information and is visible through the unit packaging:

e) identity of the contents, including the capacity of the syringe;

f) name and/or trademark and address of the manufacturer and/or his authorized representative;

g) the words “EXP” or equivalent, such as the symbol for “Use-by date” (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).

15.4 Multiple unit packs

15.4.1 General

The multiple unit packs for syringes shall be marked with the following information:

a) the words “For single use” or equivalent, such as the symbol for “Do not re-use” (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term “disposable” shall not be used;

b) name and/or trademark and address of the manufacturer and/or his authorized representative, unless the product bears this information and is visible through the multiple unit pack;

c) an identification reference to the batch code or lot number, prefixed by the symbol “Batch code” (see ISO 15223-1:2016, Table 1, symbol number 5.1.5); or the word “LOT”;

d) the external diameter and length of the needle in millimetres, if included; the gauge size of the needle may also be marked;

e) identity of the contents, including the capacity of the syringe to be used unless the information is visible through the multiple unit pack.

f) the words “EXP” or equivalent, such as the symbol for “Use-by date” (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).

15.4.2 Multiple unit packs with self-contained syringes

The multiple unit packs for self-contained syringes shall be marked with the following information:

a) the words “Syringe interior sterile” or equivalent, such as the symbol for “Sterile fluid path” (see ISO 15223-1:2016, Table 1, symbol number 5.2.9);

b) a warning to check the integrity of the seals of the self-contained syringe units before use, unless this warning is given on the syringe unit.

15.5 User packaging

The user packaging shall be marked with the following information:

a) the word “STERILE” or equivalent, such as the symbol for “Sterile” (see ISO 15223-1:2016, Table 1, symbol number 5.2.9);

b) for self-contained syringes, the words “Syringe interior sterile” or equivalent, such as the symbol for “Sterile fluid path” (see ISO 15223-1:2016, Table 1, symbol number 5.2.9);

c) the words “For single use” or equivalent, such as the symbol for “Do not reuse” (see ISO 15223-1:2016, Table 1, symbol number 5.4.2); the term “disposable” shall not be used;

d) an identification reference to the batch code or lot number, prefixed by the symbol “Batch code“(see ISO 15223-1:2016, Table 1, symbol number 5.1.5);or the word “LOT”.

e) name and/or trademark and address of the manufacturer and/or his authorized representative;

f) description of contents;

g) the words “EXP” or equivalent, such as the symbol for “Use-by date” (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).

A warning to check the integrity of the unit packaging before use may be given; such as using the symbol for “Do not use if package is damaged”. See ISO 15223-1:2016, Table 1, symbol number 5.2.8.

Symbols that indicate the sterilization method may also be used. See ISO 15223-1:2016, Table 1, symbol numbers 5.2.2 to 5.2.5.

15.6 Storage container

If user packaging comes in a storage container, the storage container shall be marked with at least the following information:

a) identity of the contents, including the capacity of the syringe;

b) an identification reference to the batch code or lot number, prefixed by the symbol “Batch code” (see ISO 15223-1:2016, Table 1, symbol number 5.1.5); or the word “LOT”;

c) the word “STERILE” or equivalent, such as the symbol for “Sterile” (see ISO 15223-1:2016, Table 1, symbol number 5.2.1);

d) the name and address of the manufacturer and, where applicable, reference to its authorized representative;

e) information for handling, storage and transportation of the contents;

f) the word “EXP” or equivalent, such as the symbol for “Use-by date” (see ISO 15223-1:2016, Table 1, symbol number 5.1.4).

Symbols that indicate the sterilization method may also be used. See ISO 15223-1:2016, Table 1, symbol numbers 5.2.2 to 5.2.5.

An indication to keep the storage container away from sunlight and keep dry may be given. See ISO 15223-1:2016, Table 1, symbol numbers 5.3.2 and 5.3.4.

15.7 Transport wrapping

If a storage container is not used but the user containers are wrapped for transportation, the information required by 15.6 shall either be marked on the wrapping or shall be visible through the wrapping.

Annex A
(normative)

Method for preparation of extracts

A.1 Principle

The syringe is filled with water in order to extract soluble components.

A.2 Apparatus and reagents

A.2.1 Distilled water.

A.2.2 Selection of laboratory borosilicate glassware.

A.3 Procedure

A.3.1 Fill at least three syringes to the nominal capacity graduation line with water (A.2.1).

A.3.2 Expel air bubbles and maintain the syringes at a temperature of 37 °C to 40 °C for 8 h to 8 h and 15 min.

A.3.3 Eject the contents and combine them in a vessel made of borosilicate glass (A.2.2).

A.3.4 Prepare the control fluid by reserving a portion of the unused water (A.2.1).

Annex B
(normative)

Test method for air leakage past syringe plunger stopper during aspiration, and for separation of plunger stopper and plunger

B.1 Principle

The syringe nozzle is connected to a compatible connection and the syringe partially filled with water. A negative pressure is applied through the nozzle, and the syringe inspected for leakage past the plunger stopper and seal(s) and to determine if the plunger stopper becomes detached from the plunger.

B.2 Apparatus and reagents

B.2.1 Tubing set with compatible conical fitting, in accordance with ISO 80369-7.

B.2.2 Support and device, for clamping the syringe plunger in a fixed position.

B.2.3 Equipment for producing, controlling and measuring vacuum, comprising a vacuum generator, a manometer and a vacuum-tight valve system, different configurations of such equipment are possible, with syringe nozzle upwards or downwards (e.g. Figure B.1).

B.2.4 Distilled water at a temperature of 18 °C to 28 °C.

B.3 Procedure

B.3.1 Draw into the syringe a volume of water (B.2.4) of not less than 25 % of the nominal capacity.

B.3.2 Withdraw the plunger stopper axially until the fiducial line is at the nominal graduated capacity and clamp (B.2.2) the plunger in this position.

B.3.3 Connect the syringe nozzle to the conical fitting (B.2.1).

B.3.4 Generate the vacuum.

B.3.5 Adjust the bleed control so that a gradual reduction in pressure is obtained and a manometer reading of 88 kPa below ambient atmospheric pressure is reached.

NOTE 1 kPa = 7,5 mmHg.

B.3.6 Examine the syringe for leakage of air past the plunger stopper or seal(s).

B.3.7 Isolate the syringe and manometer assembly by means of the vacuum-tight valve.

B.3.8 Observe the manometer reading for 60 s and record any fall in the reading.

B.3.9 Examine the syringe to determine if the plunger stopper is detached from the plunger.

B.4 Test report

The test report shall contain at least the following information:

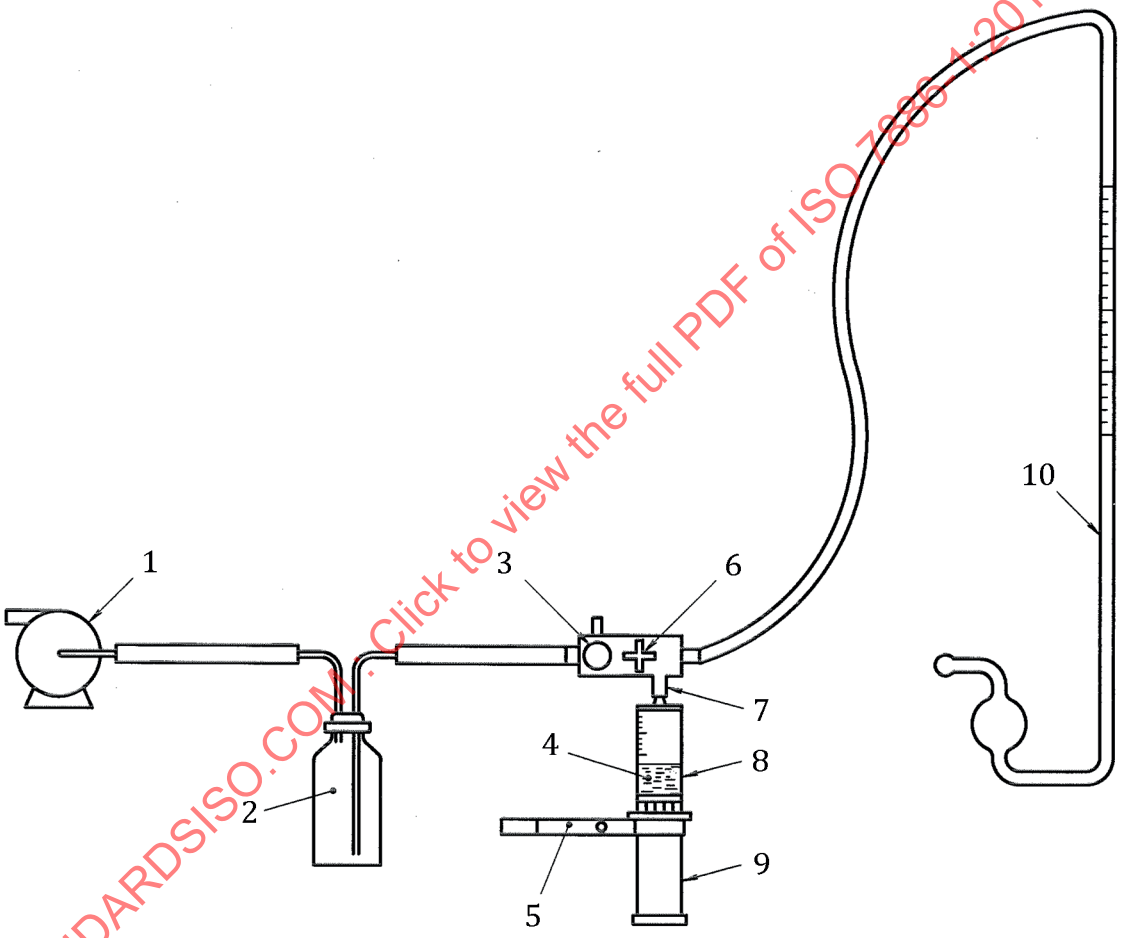
a) identity and nominal capacity of the syringe;

b) whether leakage past the plunger stopper or seal(s) was observed;

c) fall, if any, in the manometer reading;

d) whether the plunger stopper detached from the plunger;

e) date of testing.



Key

1	vacuum pump	6	vacuum-tight valve
2	bottle trap	7	female conical fitting complying with ISO 80369-7
3	fine bleed control	8	water to not less than 25 % of nominal capacity
4	nominal capacity graduation line	9	syringe
5	clamp	10	manometer

Figure B.1 — Apparatus for aspiration test

Annex C
(normative)

Method for determination of dead space

C.1 Principle

The syringe is weighed dry and after having been filled with, and emptied of, water. The dead space is inferred from the mass of the residual water.

C.2 Apparatus and reagents

C.2.1 **Balance** with a resolution of 1 mg or better.

C.2.2 **Distilled water** at a temperature of 18 °C to 28 °C.

C.3 Procedure

C.3.1 Weigh (C.2.1) the empty syringe.

C.3.2 Fill the syringe to the nominal capacity graduation line with distilled water (C.2.2), taking care to expel all air bubbles and to ensure that the level of the meniscus of the water coincides with the end of the nozzle lumen.

C.3.3 Expel the water by fully depressing the plunger, and wipe dry the outer surfaces of the syringe.

C.3.4 Reweight the syringe (C.2.1).

C.4 Calculation of results

Determine the mass, in grams, of water remaining in the syringe by subtracting the mass of the empty syringe from the mass of the syringe after expulsion of the water. Record this value as the dead space in millilitres, taking the density of water as 1 000 kg/m^3.

C.5 Test report

The test report shall contain at least the following information:

a) identity and nominal capacity of the syringe;

b) dead space, in ml;

c) date of testing.

Annex D
(normative)

Test method for liquid leakage at syringe plunger stopper under compression

D.1 Principle

The syringe is filled with water, the syringe nozzle sealed, the plunger rotated to allow the greatest downward deflection in relation to the barrel and a force applied in an attempt to induce leakage past the plunger stopper seal(s).

D.2 Apparatus and reagents

D.2.1 Device for sealing or occluding the syringe nozzle.

NOTE This can comprise the reference steel female conical fitting in accordance with ISO 80369-7, suitably sealed or occluded.

D.2.2 Device for applying a sideways force to the syringe plunger, in the range of 0,25 N to 3 N.

D.2.3 Device for generating pressures of 200 kPa and 300 kPa.

D.2.4 Distilled water at a temperature of 18 °C to 28 °C.

D.3 Procedure

D.3.1 Draw into the syringe a volume of water (D.2.4) exceeding the nominal capacity of the syringe.

D.3.2 Expel air and adjust the volume of water in the syringe to the nominal capacity.

D.3.3 Seal (D.2.1) the syringe nozzle.

D.3.4 Apply a sideways force (D.2.2) to the push-button at right angles to the plunger to swing the plunger radially about the piston seal(s) with a force as given in Table 1. Orientate the plunger to permit the maximum deflection from the axial position.

D.3.5 Apply an axial force (D.2.3) to the syringe so that the pressure given in Table 1 is generated by the relative action of the piston and barrel. Maintain the pressure for 30 s to 35 s.

D.3.6 Examine the syringe for leakage of water past the plunger stopper seal(s).

D.4 Test report

The test report shall contain at least the following information:

a) identity and nominal capacity of the syringe;

b) whether leakage past the piston or seal(s) was observed;

c) date of testing.

Annex E
(informative)

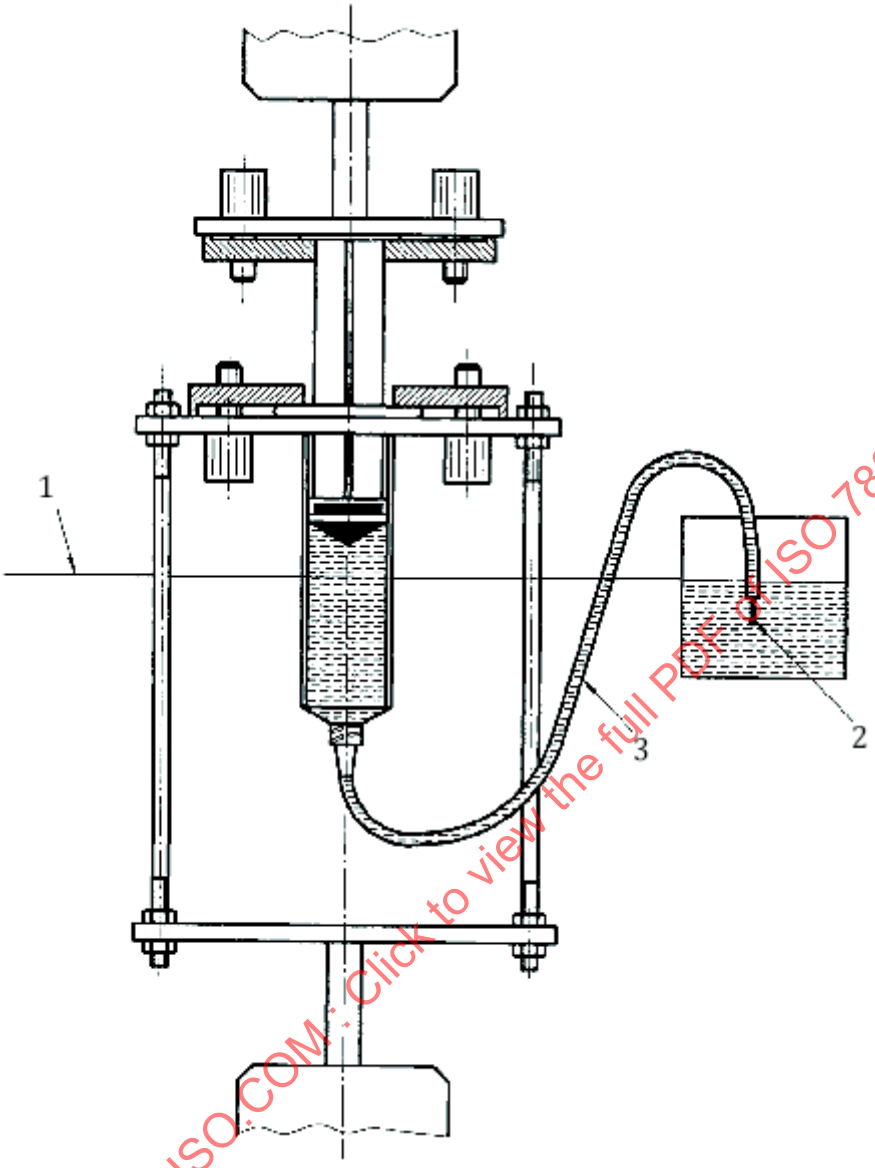
Test method for the determination of forces required to operate the piston

E.1 Principle

A mechanical testing machine is used to expel water from a syringe and simultaneously record the force required to move the piston.

E.2 Apparatus and reagents

E.2.1 Mechanical testing machine, as shown in Figure E.1, capable of attaching on to the syringe under test and of depressing the syringe piston at the constant linear rate, while simultaneously measuring and recording the force required to move the piston with an accuracy of 1 % of full-scale reading.



Key

1 water level adjusted to align with the graduation mark at 50 % of the nominal capacity of the syringe
2 needle [1,2 mm (18 G) and approximately 40 mm length]
3 tubing [(2,7 ± 0,1) mm i.d. and (500 ± 5) mm in length with male and female Luer adapters at each end)]

Figure E.1 — Apparatus for determining forces to operate piston

E.2.2 Reservoir, open to the atmosphere.

E.2.3 Tubing, (2,7 ± 0,1) mm inside diameter and (500 ± 5) mm in length and sufficient flexibility for connecting it per Figure E.1 to the sample syringe via a female Luer to barbed adapter, and to the outlet needle via a male Luer to barbed adapter.