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Introduction

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 7886-1

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/TC 84

Secretariat: **DS**

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Voting terminates on:
2026-02-23

This document is circulated as received from the committee secretariat.

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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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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 third edition cancels and replaces the second edition (ISO 7886-1:2016), which has been technically revised.

The main changes to the previous edition are the following:

— xxx xxxxxxxx xxx xxx

Drafting note: New list to be developed by WG 11.

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

The ISO 7886 series cover 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 quality management systems, e.g. ISO 9001 or 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. 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.

This document does not provide requirements for lot release. The syringes are primarily for use in humans.

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

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 23908, *Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods*

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 terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

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

3.2

dead space

volume of liquid left in syringe when the *plunger stopper* (3.12) is fully depressed during normal use

3.3

fiducial line

leading edge on the *plunger stopper* (3.12) that is in contact with and perpendicular to the syringe barrel and aligns with the zero marking on the syringe barrel when the *piston* (3.10) is fully inserted

3.4

graduated capacity

scale interval or intervals in graduation line

3.5

multiple unit pack

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

3.6

needle cap or shield

sheath intended to physically protect the needle prior to use

3.7

nominal capacity

capacity of the syringe as designated by the manufacturer

EXAMPLE 1 ml, 5 ml, 50 ml

3.8

nozzle cap

sheath intended to physically protect the nozzle prior to use

3.9

nozzle lumen

internal space or cavity within the syringe nozzle through which the fluid passes, extending from the internal end of the syringe barrel where the nozzle begins and continuing through to the tip of the nozzle

3.10

piston

assembled component of *plunger* (3.11) and *plunger stopper* (3.12)

3.11

plunger

device component which advances the *plunger stopper* (3.12) to deliver the medicinal product

3.12

plunger stopper

component connected to the leading end of the *plunger* (3.11) and seals the open end of the syringe barrel

3.13

rigid unit packaging

rigid sleeve with end cap(s), which maintains the sterility of the contents until the package is opened

3.14

self-contained syringe

syringe with protective end caps [i.e. *plunger cap*, and *nozzle cap* (3.8) or *needle cap* (3.6)] intended to maintain the sterility of the interior of the syringe

3.15

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.

3.16

unit packaging

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

3.17

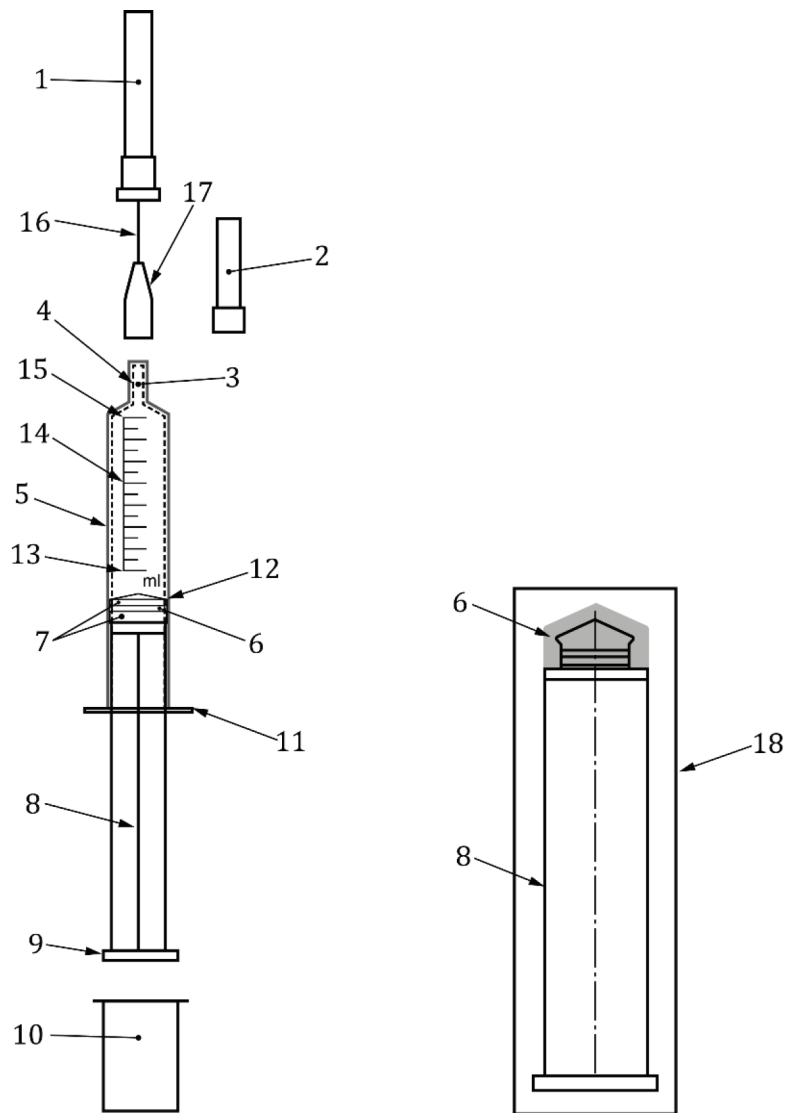
user packaging

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* ([3.5](#)).

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
- 18 piston

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 syringes for single use

5 Requirements

5.1 General requirements

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

Syringes shall be free from defects affecting appearance, safety and performance for their intended use. Syringes with integrated or add-on sharps protection shall also 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 the application of usability engineering according to IEC 62366-1.

5.2 Material selection

The materials shall satisfy the appropriate national requirements or regulations for freedom from regarding acceptable levels of pyrogens and toxins appropriate to the intended use of the product.

Materials used in the construction of the wall of the syringe barrel shall have sufficient clarity to enable the user to read dosages with normal or corrected to normal vision and environmental lighting conditions of < 100 lx, and from a reading distance of between 30 cm and 70 cm.

NOTE 1 The legibility of markings inspection is supposed to ensure that users of needle based injection systems (NIS) are able to read the markings under real life conditions (e.g. limited light intensity).

NOTE 2 The lighting levels chosen for this subclause were the lowest levels listed in ISO 8995-1 and depict ambient lighting levels that are likely to be seen in private homes or in the entrance halls, rest rooms or corridors of public spaces (e.g. hotels or hospitals). This level is chosen as representative of what patients – users of these syringes - can be expected to encounter as they look to read markings on these devices. Other lighting levels can be appropriate based on the intended use of the syringe.

The document 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.

5.3 Extraneous matter

5.3.1 General

The surfaces of the syringe that come in contact with injection fluids during normal use shall be free from particles and extraneous matter when inspected without magnification, with normal or corrected to normal vision under an illuminance of min. 500 lx, and from a reading distance of between 30 cm and 70 cm.

NOTE 1 Compliance with this requirement will be determined through inspection by an individual with normal vision (or corrected-to-normal vision), without magnification.

NOTE 2 The lighting levels chosen for this subclause were the lighting levels listed in ISO 8995-1 expected to be seen in inspection areas in the chemical, plastics or rubber industry.

5.3.2 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.

5.3.3 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).

NOTE The test to be performed whenever there is any change in construction material.

5.3.4 Pyrogenicity

Pyrogenicity mediated by endotoxin can be measured by an endotoxin-specific LAL (Limulus Amebocyte Lysate) test, referring to the specific test given in AAMI/ST72 as suggested by ISO 10993-11:2017, Annex G.

Other references to this test can be found in USP <85> and/or EU pharmacopeia.

Extraction method and testing are specified in regional and national pharmacopoeias:

- for extraction method, see USP <161>;
- for testing, see Ph.Eur., 2.6.14, method c), USP <85> and JP 4.01

5.3.5 Biocompatibility

Biocompatibility evaluation of syringes shall be in compliance to ISO 10993 series.

5.3.6 Limits for particulate matters

Sterilized syringes shall be manufactured by processes that minimize the risk of particulate contamination of the intended content.

The particle-related specifications given in pharmacopoeias (e.g. Ph.Eur., USP, JP) do not apply to empty containers but to show a certain cleanliness level, specifications have been set.

For sub-visible particles, the following applies:

- particles $\geq 10 \mu\text{m}$: 3 000 max. per syringe;
- particles $\geq 25 \mu\text{m}$: 300 max. per syringe.

NOTE These limits have been derived from the USP <788> (small volume parenterals) limit values for filled containers with a nominal volume of less than 100 ml. The limits, which is 50 % of the USP <788>, have been chosen based on historical proven capability using the light obscuration method as given in [Annex G](#).

5.4 Lubricant

For lubricants applied to interior surface of the syringe, the quantity of lubricant applied shall not exceed $0,25 \text{ mg/cm}^2$ 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.