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Sterile injection syringes

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Foreword

This Japanese Industrial Standard has been revised by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Medical Technology Association of Japan (MTJAPAN)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied mutatis mutandis pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS T 3210** : 2011), which has been technically revised.

However, **JIS T 3210** : 2011 remains valid for three years from the date of public notice of the revision of this Standard.

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Sterile injection syringes

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 7886-1** : 2017, Edition 2, with some modifications of the technical contents to reflect actual situations in Japan.

The vertical lines on both sides and dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies requirements for sterile hypodermic syringes (hereafter referred to as syringes), with or without needle, made of plastic or other materials. This Standard does not provide requirements for lot release. The syringes are primarily for use in humans.

Sterile syringes specified in this Standard 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 Standard are intended for use with hypodermic needles specified in **JIS T 3209**.

NOTE The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 7886-1 : 2017 *Sterile hypodermic syringes for single use — Part 1 : Syringes for manual use* (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

2 Normative references

Part or all of the provisions of the following standards, through reference in this text, constitute provisions of this Standard. For standards indicated below, the most recent editions (including amendments) shall be applied.

JIS T 0993-1 *Biological evaluation of medical devices — Part 1 : Evaluation and testing within a risk management process*

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*

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 purpose of this Standard, the following terms and definitions apply.

3.1

nominal capacity

capacity of the syringe as designated by the manufacturer

Example 1 ml, 5 ml, 50 ml

3.2

nominal capacity graduation

graduation to indicate the nominal capacity

3.3

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 plunger is fully inserted

3.4

unit packaging

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

3.5

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.

3.6

three-piece syringe

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

3.7

nozzle cap

sheath intended to physically protect the nozzle prior to use

3.8

plunger stopper

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

3.9

self-contained syringe

syringe with protective end caps [i.e. plunger cap, and needle cap or shield (3.14)] intended to maintain the sterility of the interior of the syringe

3.10

dead space

residual volume of fluid left in syringe barrel and nozzle when the plunger stopper (3.8) is fully depressed

3.11

multiple unit pack

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

3.12

piston

assembled component of plunger and plunger stopper (3.8)

3.13

barrel flanges

flanges that protrude from the barrel to provide the user an ergonomic means of gripping the syringe during injection

Note 1 to entry... Barrel flanges are also referred to as finger grips.

3.14

needle cap or shield

sheath intended to physically protect the needle prior to use

3.15

plunger

device component which advances the plunger stopper to deliver the medicinal product

3.16

service graduation

graduation extended beyond the nominal capacity graduation

3.17**long graduation line**

graduation line marked with the figures representing a certain capacity which is in accordance with the nominal capacity

3.18**short graduation line**

graduation line marked between the long graduation line and next long graduation line

3.19**minimum length of scale**

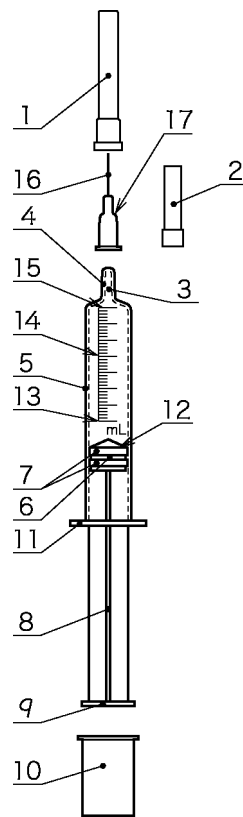
length from zero graduation to nominal capacity graduation

3.20**purified water**

“purified water” specified in Official Monographs of Japanese Pharmacopoeia or water at least equivalent thereto in quality

4 Configuration and names of parts

Schematic representation of hypodermic syringes for single use is shown in Figure 1.



Key

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

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 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 test-

ing.

- 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.
 - This 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 Physical and chemical requirements

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 purified 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 purified water to the finished syringe product shall not change its content of metals by more than a combined total of 5 mg/L of lead, tin, zinc and iron; the cadmium content shall be less than 0.1 mg/L.

Compliance with this requirement shall be demonstrated by preparing the solutions described in Annex A and testing them using an atomic absorption method or a recognized micro-analytical method at least equivalent to this.