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(MTJAPAN/JSA)

**Needle-based injection systems for
medical use—Part 2: Needles—
Requirements and test methods**

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Contents

	Page
Introduction.....	1
1 Scope.....	1
2 Normative references	1
3 Terms and definitions	2
4 Requirements	4
4.1 Materials	4
4.2 Dimensions	4
4.3 Determination of flow rate through the needle	4
4.4 Bond between hub and needle tube	4
4.5 Needle points	5
4.6 Freedom from defects	5
4.7 Lubrication	5
4.8 Dislocation of measuring point at patient end	5
4.9 Determination of functional compatibility with needle-based injection systems	5
4.10 Ease of assembly and disassembly	5
4.11 Sterility	5
5 Sampling	6
6 Pre-conditioning of needles	6
6.1 Pre-conditioning in a dry-heat atmosphere	6
6.2 Pre-conditioning in a cold-storage atmosphere	6
6.3 Pre-conditioning in a cyclical atmosphere	6
7 Standard atmosphere and apparatus for tests	7
7.1 General	7
7.2 Standard test atmosphere	7
7.3 Test gauge	7
8 Determination of dislocation of measuring point at patient end	8
9 Bond between hub and needle tube	8
10 Packaging.....	9
11 Test method for validating the compatibility of needles and injector systems	9
11.1 Principle	9
11.2 Apparatus	9
11.3 Sample quantity requirements	10

11.4	Procedure	10
11.5	Acceptance criteria	12
11.6	Test report	13
12	Information supplied by the manufacturer	13
12.1	General	13
12.2	Marking	13
12.3	Instructions for use	15
Annex A (normative)	Determination of flow rate through needle	16
Bibliography		18
Annex JA (informative)	Comparison table between JIS and corresponding International Standard	19

Foreword

This translation has been made based on the original Japanese Industrial Standard 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 the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 3226-2:2011** is replaced with this Standard.

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JIS T 3226 series consists of the following 2 parts under the general title “*Needle-based injection systems for medical use*”:

Part 1: Needle-based injection systems—Requirements and test methods

Part 2: Needles—Requirements and test methods

Needle-based injection systems for medical use—Part 2: Needles— Requirements and test methods

Introduction

This Japanese Industrial Standard has been prepared based on the second edition of **ISO 11608-2** published in 2012 with some modifications of the technical contents so as to reflect the actualities in Japan.

The portions given dotted underlines are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies requirements and test methods for single-use, double-ended, sterile needles for needle-based injection systems (NISs) that fulfil the specifications of **JIS T 3226-1** (hereafter referred to as “needles”). It is not applicable to:

- needles for dental use;
- pre-filled syringe needles;
- needles pre-assembled by the manufacturer;
- needles not requiring assembly or attachment to the NIS.

NOTE 1 **JIS T 3226-2:2011** may be applied until 30 September, 2018.

NOTE 2 The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 11608-2:2012 *Needle-based injection systems for medical use—Requirements and test methods—Part 2: Needles* (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

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the year indication, only the editions of the indicated year shall be applied and the revisions (including amendments) made thereafter shall not be applied. For those without the indication of the year, the most recent edition (including amendments) shall be applied.

JIS C 60068-2-30:2011 *Environmental testing—Part 2-30: Tests—Test Db: Damp heat, cyclic (12 h + 12 h cycle)*

NOTE : Corresponding International Standard: IEC 60068-2-30:2005 *Environmental testing—Part 2-30: Tests—Test Db: Damp heat, cycle (12 h + 12 h cycle)* (IDT)

JIS G 4305:2012 *Cold-rolled stainless steel plate, sheet and strip*

JIS T 0307:2004 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

JIS T 3209:2011 *Sterile injection needles*

NOTE : Corresponding International Standard: ISO 7864:1993 *Sterile hypodermic needles for single use* (MOD)

JIS T 3226-1 *Needle-based injection systems for medical use—Part 1: Needle-based injection systems—Requirements and test methods*

NOTE : Corresponding International Standard: ISO 11608-1 *Needle-based injection systems for medical use—Requirements and test methods—Part 1: Needle-based injection systems* (MOD)

JIS Z 9015-1:2006 *Sampling procedures for inspection by attributes—Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

NOTE : Corresponding International Standard: ISO 2859-1:1999 *Sampling procedures for inspection by attributes—Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection* (IDT)

ISO 9626:1991 *Stainless steel needle tubing for the manufacture of medical devices and its Amendment 1:2001*

ISO 15510 *Stainless steels—Chemical composition*

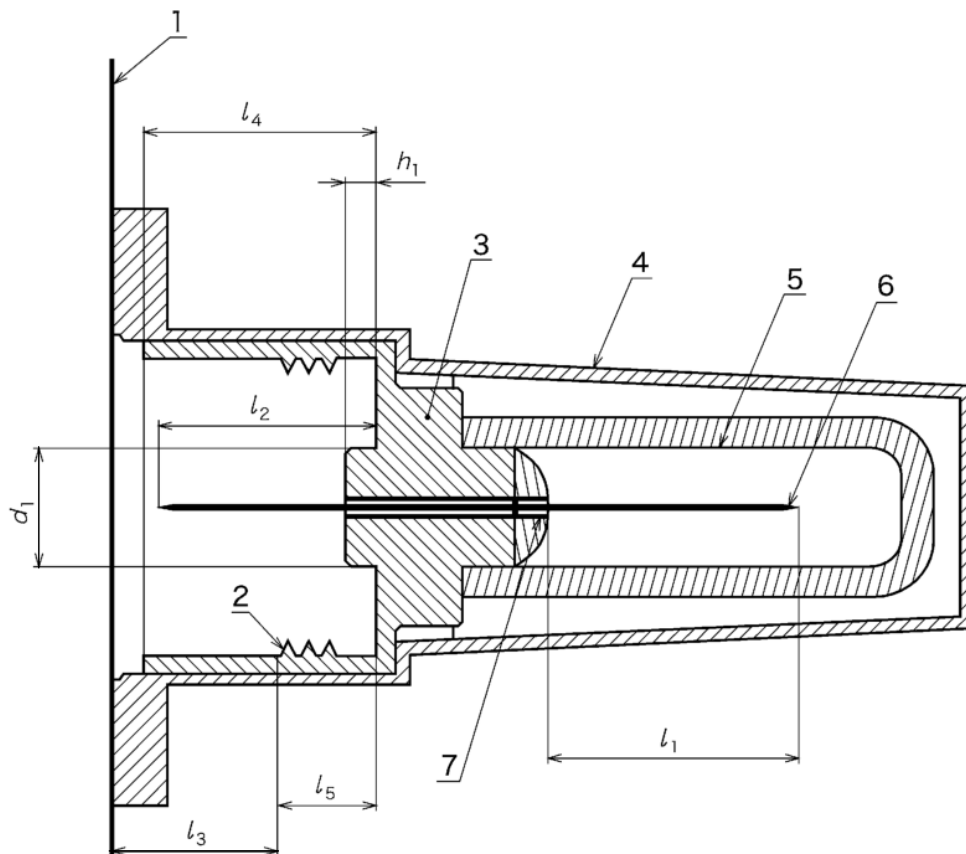
3 Terms and definitions

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

3.1 NIS, needle-based injection system

injection system intended for parenteral administration by injection of medicinal products using a needle and a multi-dose or single-dose container

See Figure 1.



- 1 seal
- 2 means of needle assembly attachment
- 3 needle hub
- 4 needle container
- 5 needle shield (not required)
- 6 needle tube
- 7 jointing medium (if used)

NOTE : The needle container may serve as a needle shield.

Figure 1 Example presentation of needle assembly for a NIS

3.2 unit packaging

needle container, together with the seal forming the packaging of the device, that maintains the sterility of the needle

3.3 user packaging

what is provided to the user with one or a collection of devices, in their unit packaging, of the same item and from the same manufacturing batch

3.4 seal

removable barrier which is intended to maintain the sterility of the needle inside the needle container

4 Requirements

4.1 Materials

The needle shall be made of materials SUS304, SUS304L or SUS321 specified in **JIS G 4305**:2012 or stainless steels specified in **ISO 9626**:1991 or **ISO 15510**.

4.2 Dimensions

4.2.1 General

The dimensions of the tubes shall be as given in Table 1 of **ISO 9626**:1991 and Table 2 of **ISO 9626**:1991/Amd. 1:2001.

The dimensions of the needle assembly attachment part (l_2 , l_3 , l_4 and l_5 in Table 1) shall be such that the needle fits and functions with NISs that meet the requirements specified in **JIS T 3226-1**.

Needles shall be classified into Type A and non-Type A.

4.2.2 Type A needles

Type A needles shall fit the thread of the test apparatus specified in **7.3** and function with pen-injectors designed and labelled to be used with Type A needles.

Dimensions shall be in accordance with Table 1.

Table 1 Dimensional requirements of needle assembly

Unit: mm

Measurements	Dimensions
l_1	specified length ± 1.25
l_2	5.7 to 7.0
l_3	< 6.0
l_4	< 7.5
l_5	< 3.9
h_1	0 to 1.0
d_1	0 to 3.0

4.2.3 Non-Type A needles

Non-Type A needles shall fit NIS which is designed and marked to be used for specific non-Type A needles.

4.3 Determination of flow rate through the needle

The needle shall be tested in accordance with Annex A to determine the flow rate through the needle, in millilitres per minute.

4.4 Bond between hub and needle tube

The union of the hub and needle tube shall not break when tested in accordance with clause **9**.