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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	3
4.1 Materials	3
4.2 Dimensions	3
4.3 Determination of flow rate through the needle	4
4.4 Bond between hub and needle tube	4
4.5 Needle points	4
4.6 Freedom from defects	4
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	5
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	9
10 Packaging	9
11 Test method for validating the compatibility of needles and injector systems	9
11.1 Principle	9
11.2 Apparatus	10
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	14
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 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 3226-2** : 2015), which has been technically revised.

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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

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

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 11608-2** : 2012, Edition 2, with some modifications of the technical contents to reflect the local conditions in Japan.

The 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 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 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**.

The previous edition of this Standard, **JIS T 3226-2** : 2015, remains valid for three years from the date of public notice of the revision of this Standard.

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 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 editions (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 Normative reference in the corresponding International Standard: IEC