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(MTJAPAN/JSA)

**Sterile infusion administration set —
Part 4: Sterile infusion sets for single use,
gravity feed**

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Contents

	Page
Introduction	1
1 Scope	1
2 Normative references	1
2A Terms and definitions	2
3 General requirements	4
4 Designation (excluded in this Standard)	7
5 Materials	7
6 Physical requirements	7
6.1 Particulate contamination	7
6.2 Leakage	7
6.3 Tensile strength	7
6.4 Closure-piercing device	7
6.5 Air-inlet device	8
6.6 Tubing	8
6.7 Fluid filter	8
6.8 Drip chamber and drip tube	9
6.9 Flow regulator	9
6.10 Flow rate of infusion fluid (excluded in this Standard)	9
6.11 Injection site	9
6.12 Male conical fitting	9
6.13 Protective caps	9
7 Chemical requirements	9
7.1 Eluting material	9
8 Biological requirements	11
8.1 General	11
8.2 Sterility	11
8.3 Pyrogenicity	11
8.4 Haemolysis	11
8.5 Toxicity	11
9 Labelling	11
9.1 General	11
9.2 Unit container	12
9.3 Shelf or multi-unit container	12
10 Packaging	13
10.1 Unit container	13

10.2 Shelf or multi-unit container	13
Annex A (normative) Physical tests	14
Annex B (normative) Chemical tests	17
Annex C (normative) Biological tests	19
Annex JA (informative) Comparison table between JIS and corresponding International Standard	20

Foreword

This Japanese Industrial Standard has been established by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal for establishment 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.

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JIS T 3211 series consists of the following 7 parts under the general title *Sterile infusion administration set* :

Part 4 : Sterile infusion sets for single use, gravity feed

Part 5 : Sterile burette infusion sets for single use

Part 8 : Sterile infusion sets for single use with pressure infusion apparatus

Part 9 : Sterile fluid lines for single use

Part 10 : Sterile accessories for fluid lines for single use

Part 11 : Sterile infusion filters for single use

Part 12 : Sterile check valves for single use

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Sterile infusion administration set — Part 4 : Sterile infusion sets for single use, gravity feed

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 8536-4** : 2010, Edition 5 and Amendment 1 : 2013 with some modifications of the technical contents to reflect the actual situation in Japan. The amendment to the said International Standard has been compiled in this Standard.

The vertical lines on both sides of the text 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 single use, gravity feed sterile infusion sets for medical use (hereafter referred to as infusion sets).

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

ISO 8536-4 : 2010 *Infusion equipment for medical use — Part 4 : Infusion sets for single use, gravity feed* and Amendment 1 : 2013 (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 T 0993-1 : 2012 *Biological evaluation of medical devices — Part 1 : Evaluation and testing within a risk management process*

NOTE Corresponding International Standard : ISO 10993-1 *Biological evaluation of medical devices — Part 1 : Evaluation and testing within a risk management process* (MOD)

JIS T 3209 *Sterile injection needles*

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

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