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JIS T 3211-10 : 2019

(MTJAPAN/JSA)

**Sterile infusion administration set —
Part 10: Sterile accessories for fluid
lines for single use**

ICS 11.040.20

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Contents

	Page
Introduction	1
1 Scope	1
2 Normative references	1
2A Terms and definitions	2
3 Materials	3
4 Physical requirements	3
4.1 Avoidance of air bubbles	3
4.2 Particulate contamination	3
4.3 Tensile strength	3
4.4 Leakage	3
4.5 Adapters with female and/or male conical fittings	3
4.6 Protective caps	3
4.7 Manipulation of stopcocks	3
4.8 Unit with injection site	3
4.9 Unit with check valve	3
5 Chemical requirements	4
6 Biological requirements	4
6.1 Sterility	4
6.2 Pyrogens	4
6.3 Haemolysis	4
7 Packaging	4
8 Labelling	4
8.1 General	4
8.2 Label on unit container	4
8.3 Label on shelf or multi-unit container	5
Annex A (normative) Physical tests	6
Annex B (normative) Chemical tests	7
Annex C (normative) Biological tests	8
Annex JA (informative) Comparison table between JIS and corresponding International Standard	9

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

Sterile infusion administration set — Part 10 : Sterile accessories for fluid lines for single use

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 8536-10** : 2015, Edition 2, with some modifications of the technical contents to reflect the needs and conditions unique to 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 applies to sterile accessories for fluid lines for single use (hereafter referred to as accessories) intended to be used with gravity-feed infusion sets specified in **JIS T 3211-4** and infusion sets with pressure infusion apparatus specified in **JIS T 3211-8**.

This Standard includes the following :

- a) two-way stopcocks (2SC), three-way stopcocks (3SC), four-way stopcocks, and stopcocks manifold (SM);

NOTE 1 Designation of a stopcock depends on the number of connections. The number of possible functional positions can be expressed by addition of a complementary note, using a diagonal stroke and a numeral indicating the number of possible stopcock positions, e.g. 3/4-way stopcock for three-way stopcock with four possible positions.

- b) units with injection site (UIS);
- c) stoppers or adapters.

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

ISO 8536-10 : 2015 *Infusion equipment for medical use — Part 10 : Accessories for fluid lines for single use with pressure infusion equipment* (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 amend-