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JIS T 3211-8 : 2019

(MTJAPAN/JSA)

**Sterile infusion administration set —  
Part 8: Sterile infusion sets for single use  
with pressure infusion apparatus**

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

## Introduction

This Japanese Industrial Standard has been prepared based on **ISO 8536-8:2015**, Edition 2, with some modifications of the technical contents to reflect the actual situation 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 for sterilized infusion sets for single use with pressure infusion apparatus up to a maximum of 200 kPa (2 bar) (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 8536-8 : 2015** *Infusion equipment for medical use — Part 8 : Infusion sets for single use with pressure infusion apparatus* (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standards 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 3211-4 *Sterile infusion administration set — Part 4 : Sterile infusion sets for single use, gravity feed*

**NOTE** Corresponding International Standard : ISO 8536-4 *Infusion equipment for medical use — Part 4 : Infusion sets for single use, gravity feed* (MOD)

ISO 15223-1 *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 : General requirements*

ISO 80369-7 : 2016 *Small-bore connectors for liquids and gases in healthcare ap-*