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**Sterile infusion administration set**

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In the event of any doubts arising as to the contents,  
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## 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 Japan Medical Devices Manufacturers Association (JMED)/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 3211 : 2005 is replaced with this Standard.

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Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, or utility model right which have technical properties. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public or utility model right which has the said technical properties.

# Sterile infusion administration set

## Introduction

This Japanese Industrial Standard has been prepared based on the third edition of ISO 8536-4 published in 2004, the second edition of ISO 8536-5 published in 2004, and the first editions of ISO 8536-8, ISO 8536-9 and ISO 8536-10 published in 2004 with some modifications of the technical contents in order to harmonize with the actual conditions in Japan.

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

## 1 Scope

This Standard specifies sterile infusion administration sets for infusing infusion solution (hereafter referred to as “infusion sets”) which are ready to use and for single use.

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

ISO 8536-4:2004 *Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed*

ISO 8536-5:2004 *Infusion equipment for medical use—Part 5: Burette infusion sets for single use, gravity feed*

ISO 8536-8:2004 *Infusion equipment for medical use—Part 8: Infusion equipment for use with pressure infusion apparatus*

ISO 8536-9:2004 *Infusion equipment for medical use—Part 9: Fluid lines for use with pressure infusion equipment*

ISO 8536-10:2004 *Infusion equipment for medical use—Part 10: Accessories for fluid lines for use with pressure infusion equipment* (Overall evaluation : 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.

JIS T 3211 : 2005 may be applied until July 28 in 2014.

## 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 apply but the revisions (including amendments) made thereafter shall not apply. For those without the indication of the year, the most recent edition (including amendments) shall apply.