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(MTJAPAN/JSA)

**Sterile infusion administration set —
Part 12: Sterile check valves for single
use**

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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 12 : Sterile check valves for single use

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 8536-12** : 2007, Edition 1, and its Amendment 1 (2012) with some modifications of the technical contents to reflect the needs and conditions unique to Japan. The amendment to the said International Standard has been incorporated into this Standard.

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 sterilized check valves intended for single use (hereafter referred to as check valves) and used with gravity-feed infusion equipment and/or infusion equipment with pressure infusion apparatus.

The functional requirements in this Standard also apply to built-in check valves.

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

ISO 8536-12 : 2007 *Infusion equipment for medical use — Part 12 : Check valves* and Amendment 1 : 2012 (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 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*