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(MTJAPAN/JSA)

Sterile blood transfusion set—Part 4: Sterile transfusion sets for single use, gravity feed

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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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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.

Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, applications for a patent after opening to the public or utility model rights. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, applications for a patent after opening to the public or utility model rights.

JIS T 3212 series consists of the following 2 parts under the general title *Sterile blood transfusion set*:

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

Part 5: Sterile transfusion sets for single use with pressure infusion apparatus

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Sterile blood transfusion set—Part 4: Sterile transfusion sets for single use, gravity feed

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 1135-4**:2015, Edition 6, with some modifications of the technical contents to reflect the needs and conditions unique to Japan.

The vertical lines on both sides 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 sterile single-use transfusion gravity sets for medical use in order to ensure their compatibility with containers for blood and blood components as well as with intravenous equipment.

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

ISO 1135-4:2015 *Transfusion equipment for medical use—Part 4: Transfusion sets for single use, gravity feed* (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 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*

JIS T 3209 *Sterile injection needles*

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

JIS T 3217:2016 *Plastic collapsible containers for human blood and blood components*