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Sterile blood transfusion set

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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 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 3212** : 2005 is replaced with this Standard.

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 blood transfusion set

Introduction

This Japanese Industrial Standard has been prepared based on the third edition of **ISO 1135-4** published in 2004 with some modifications of the technical contents in order to harmonize with the actual conditions in Japan.

The portions with continuous sidelines or dotted underlines are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies the sterile blood transfusion sets for the transfusion of blood preparations such as preserved blood (hereafter referred to as "transfusion sets") that are ready to use and single-use.

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

ISO 1135-4:2004 *Transfusion equipment for medical use—Part 4: Transfusion sets for single use* (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 3212: 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 edition of the indicated year shall apply but the revisions (including amendments) made thereafter shall not apply.

JIS T 0307 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

NOTE : Corresponding International Standard : **ISO 15223** *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied* and Amendment 1 (IDT)

JIS T 0993-1 *Biological evaluation of medical devices—Part 1: Evaluation and testing*

NOTE : Corresponding International Standard : **ISO 10993-1**: 2003 *Biological evaluation of medical devices—Part 1: Evaluation and testing* (IDT)