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Plastic collapsible containers for human blood and blood components

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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 revised by the 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 Medical Technology Association of Japan (MTJAPAN)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied mutatis mutandis pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS T 3217** : 2016), which has been technically revised.

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

Plastic collapsible containers for human blood and blood components

Introduction

This Japanese Industrial Standard has been prepared based on ISO 3826-1 : 2019, Edition 3, with the following changes to reflect local conditions in Japan: exclusion of products containing anticoagulant and preservative solutions from the scope because these products require special approval for manufacture in Japan by Pharmaceuticals and Medical Devices Agency (PMDA); and replacement of bottle needle dimensions of ISO 1135-4 and ISO 1135-5 with those of relevant JISs that are compatible with transfusion sets distributed in 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 plastics collapsible containers for the collection, storage, processing, transport, separation and administration of blood and blood components (hereafter referred to as plastics containers).

This Standard does not apply to products containing anticoagulant and preservative solutions.

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

ISO 3826-1 : 2019 *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers* (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.

The previous edition of this Standard, JIS T 3217 : 2016, remains valid for three years from the date of public notice of the revision of this Standard.

2 Normative references

Part or all of the provisions of the following standards, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS T 0993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

JIS T 3212-4 *Sterile blood transfusion set — Part 4: Sterile transfusion sets for*