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(MTJAPAN/JSA)

Evacuated single-use containers for human venous blood specimen collection

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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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Contents

Page

Foreword

This Japanese Industrial Standard has been 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 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 3233** : 2011), 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 Ministers and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, published patent application or utility model rights.

Evacuated single-use containers for human venous blood specimen collection

Introduction

This Japanese Industrial Standard has been prepared based on ISO 6710 : 2017, Edition 2, with some modifications of the technical contents for only the parts relating to evacuated single-use containers for venous blood specimen collection in order to harmonize with the actual conditions 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 and test methods for sterile evacuated single-use containers for venous blood specimen collection (hereafter referred to as evacuated containers), ready to use, by means of evacuation already induced by the manufacturer.

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

ISO 6710 : 2017 *Single-use containers for human venous blood specimen collection* (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.

However, JIS T 3233 : 2011 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. 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 editions (including amendments) shall be applied.

ISO 11137 (all parts) *Sterilization of health care products — Radiation*

ISO 17665-1 : 2006 *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 80369-7 *Small-bore connectors for liquids and gases in healthcare applica-*