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Sterile, single-use intravascular catheters

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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 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 3268** : 2018), 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.

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Sterile, single-use intravascular catheters

Introduction

This Japanese Industrial Standard has been prepared based on ISO 10555-1 : 2013, Edition 2 and Amendment 1 : 2017, and ISO 10555-3 : 2013, Edition 2 and ISO 10555-4 : 2013, Edition 2 with some modifications of the technical contents, reflecting the real conditions in Japan. The amendment(s) to the said International Standard(s) has been incorporated into this Standard.

The dotted underlines indicate additions to the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies sterile, single-use intravascular catheters (hereafter referred to as catheters) which are designed to be inserted or implanted into vessels (including AV shunts and vascular grafts) or to deliver medical devices to the chosen location. However, this Standard does not apply to catheters coated with biologically derived materials such as heparin and urokinase in order to maintain antithrombogenicity, catheters coated with antibacterial agent in order to render the catheters antimicrobial or hydratable intravascular catheters.

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

ISO 10555-1 : 2013 *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements* + Amendment 1 : 2017

ISO 10555-3 : 2013 *Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters*

ISO 10555-4 : 2013 *Intravascular catheters — Sterile and single-use catheters — Part 4: Balloon dilatation catheters* (overall evaluation: 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 3268 : 2018 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*