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Sterile, single-use intravascular catheters

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Mita MT Building, 3-13-12, Mita, Minato-ku, Tokyo, 108-0073 JAPAN

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 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 3268**:2012 is replaced with this Standard.

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.

Sterile, single-use intravascular catheters

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 10555-1**:2013, Edition 2 (including the corrected version published in 2014), **ISO 10555-3** and **ISO 10555-4** with some modifications of the technical contents, reflecting the circumstances in Japan.

The dotted underlines indicate changes from the corresponding International Standards. 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) for diagnostic or therapeutic purposes, or to deliver medical devices to the chosen location. However, this Standard does not apply to catheters with anti-thrombogenic property, coated with biological materials such as heparin and urokinase, catheters with antibacterial effect, coated with antimicrobial agents, and hydratable catheters.

NOTE 1 **JIS T 3268**:2012 may be applied until January 31, 2021.

NOTE 2 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* and the corrected version:2014

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 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 indicated below, only the editions of the indicated year shall be applied and any revisions (including amendments) made thereafter shall not be applied.

JIS T 0307:2004 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

JIS T 0993-1:2012 *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process*