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Central venous catheters

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In the event of any doubts arising as to the contents,
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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 3218:2012** is replaced with this Standard.

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Central venous catheters

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 10555-1** : 2013, Edition 2 (including the corrected version published in 2014) and **ISO 10555-3** : 2013, Edition 2, with some modifications of the technical contents, reflecting the real conditions 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 requirements for sterilized, single-use central venous catheters for the purpose of injecting drug solution, taking blood, measuring venous pressure, etc. (hereafter referred to as catheters), and requirements for the guidewire, dilator, introducer needle, introducer catheter and sheath introducer, which are used for insertion and placement of catheters. 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, hydratable catheters or catheters with oxygen saturation determination function.

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*

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