

## JAPANESE INDUSTRIAL STANDARD

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(MTJAPAN/JSA)

Sterile, single-use intravascular catheters-over-needle peripheral 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 3223: 2016), which has been technically revised.

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# Sterile, single-use intravascular catheters — over-needle peripheral catheters

JIS T 3223: 2023

#### Introduction

This Japanese Industrial Standard has been prepared based on **ISO 10555-5**: 2013, Edition 2, with some modifications of the technical contents to reflect the actual situation 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 over-needle peripheral intravascular catheters (hereafter referred to as catheters), intended for accessing the peripheral vascular system, supplied in the sterile condition and intended for single use.

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

ISO 10555-5: 2013 Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters (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 3223**: 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. For those standards, the most recent editions (including amendments) shall be applied.

JIS G 4305 Cold-rolled stainless steel plate, sheet and strip

ISO 9626 Stainless steel needle tubing for the manufacture of medical devices— Requirements and test methods

ISO 10555-1 Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements

ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications