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Sterile injection needles

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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 3209** : 2011), which has been technically revised.

However, **JIS T 3209** : 2011 remains valid for three years from the date of public notice of the revision of this Standard.

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Sterile injection needles

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 7864** : 2016, Edition 4, with some modifications of the technical contents to reflect actual situations in Japan.

The 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 sterile injection needles for single use of 0.18 mm to 1.2 mm in nominal outer diameter.

It does not apply to dental needles and pen needles.

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

ISO 7864 : 2016 *Sterile hypodermic needles for single use — Requirements and test methods* (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**.

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.

JIS G 4305 : 2021 *Cold-rolled stainless steel plate, sheet and strip*

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

NOTE Normative reference in the corresponding International Standard : ISO 10993-1 *Biological evaluation of medical devices — Part 1 : Evaluation and testing within a risk management process*

ISO 6009 *Hypodermic needles for single use — Colour coding for identification*

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

ISO 15223-1 *Medical devices — Symbols to be used with medical device labels,*