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Single-use needle for infusion port

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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 (MT JAPAN)/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 3221** : 2011), which has been technically revised.

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Single-use needle for infusion port

1 Scope

This Japanese Industrial Standard specifies requirements for sterile single-use needles for infusion port (hereafter referred to as needles for infusion port).

However, **JIS T 3221 : 2011** 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 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*

JIS T 3210 : 2022 *Sterile injection syringes*

ISO 3696 *Water for analytical laboratory use — Specification and test methods*

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

ISO 9626 : 2016 *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

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

3 Terms and definitions

For the purpose of this Standard, the following terms and definitions apply.

3.1

nominal outside diameter

dimension of the outside diameter of needle tube, which is indicated on the encapsulation or container of the needle for infusion port

3.2

nominal length

dimension of the length of needle tube, which is indicated on the encapsulation or container of the needle for infusion port