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Sterile blood collection 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 (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 3220** : 2011), which has been technically revised.

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Sterile blood collection needles

1 Scope

This Standard specifies requirements for single-use sterile blood collection needles (hereafter referred to as blood collection needles), which are used in combination with evacuated blood collection containers and capable of immediate blood collection by multiple evacuated containers in succession.

However, **JIS T 3220 : 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 3209 *Sterile injection needles*

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

double-ended needle type

blood collection needle used exclusively for an evacuated blood collection container, which consists of needle tube, needle hub and rubber sleeve

Note 1 to entry See Figure 1.

3.2

winged needle type

blood collection needle with a winged needle, which consists of puncture needle, wing,