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Sterile injection syringes

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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 3210** : 2011), which has been technically revised.

However, **JIS T 3210** : 2011 remains valid for three years from the date of public notice of the revision of this Standard.

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Sterile injection syringes

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 7886-1** : 2017, Edition 2, with some modifications of the technical contents to reflect actual situations 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 sterile hypodermic syringes (hereafter referred to as syringes), with or without needle, made of plastic or other materials. This Standard does not provide requirements for lot release. The syringes are primarily for use in humans.

Sterile syringes specified in this Standard are intended for use immediately after filling and are not intended to contain the medicament for extended periods of time.

It excludes syringes for use with insulin (see **ISO 8537**), single-use syringes made of glass, syringes for use with power-driven syringe pumps, syringes pre-filled by the manufacturer, and syringes intended to be stored after filling (e.g. in a kit for filling by a pharmacist).

Hypodermic syringes without a needle specified in this Standard are intended for use with hypodermic needles specified in **JIS T 3209**.

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

ISO 7886-1 : 2017 *Sterile hypodermic syringes for single use — Part 1 : Syringes for manual use* (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 indicated below, the most recent editions (including amendments) shall be applied.

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

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