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Needle-based injection systems for medical use — Part 1: Needle-based injection systems — Requirements and test methods

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Mita Avanti, 3-11-28, Mita, Minato-ku, Tokyo, 108-0073 JAPAN

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 3226-1** : 2015), which has been technically revised.

Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, published patent application or utility model rights. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, published patent application or utility model rights.

JIS T 3226 series consists of the following 2 parts under the general title *Needle-based injection systems for medical use* —:

Part 1: Needle-based injection systems — Requirements and test methods

Part 2: Needles — Requirements and test methods

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Needle-based injection systems for medical use — Part 1: Needle-based injection systems — Requirements and test methods

Introduction

This Japanese Industrial Standard has been prepared based on ISO 11608-1 : 2014, Edition 3, with some modifications of the technical contents to reflect the local conditions in Japan.

Annex JA contains requirements for containers that are unique to JIS and not given in the corresponding International Standard.

The dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JB.

1 Scope

This Standard specifies requirements and test methods for needle-based injection systems (NISs) intended to be used with needles and with replaceable or non-replaceable containers. Containers covered in this Standard include single- and multi-dose syringe-based and cartridge-based systems, filled either by the manufacturer or by the end-user.

Additional guidance for NISs equipped with electronic or electromechanical components and NISs equipped with automated functions is given in ISO 11608-4 and ISO 11608-5 respectively.

Needle-free injectors, and requirements relating to methods or equipment associated with end-user filling of containers, are outside the scope of this Standard.

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

ISO 11608-1 : 2014 *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems* (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.

The previous edition of this Standard, JIS T 3226-1 : 2015, 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