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(MTJAPAN/JSA)

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

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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 translation has been made based on the original Japanese Industrial Standard 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 the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 3226-1**:2011 is replaced with this Standard.

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

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 the second edition of **ISO 11608-1** published in 2012 with some modifications of the technical contents so as to reflect the actualities in Japan.

The portions given dotted underlines are the matters in which the contents of the corresponding International Standard have been modified. 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 1 **JIS T 3226-1**:2011 may be applied until 30 September, 2018.

NOTE 2 The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 11608-1:2012 *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**.

2 Normative references

The following standards contain provisions which, 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 edition (including amendments) shall be applied.