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(JMED/JSA)

Sterile infusion filter

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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 Japan Medical Devices Manufacturers Association (JMED)/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 3219 : 2005** is replaced with this Standard.

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Sterile infusion filter

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of **ISO 8536-11** published in 2004 with some modifications of the technical contents in order to harmonize with the actual conditions in Japan.

The portions with continuous sidelines or dotted underlines in this Standard 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 JA.

1 Scope

This Standard specifies single-use sterile infusion filters (hereafter referred to as “infusion filters”), which infuse after removal of particulate foreign matters, bacteria and fungi in infusion and are ready to use. However, the removal sizes and species of particulate foreign matters, bacteria and fungi depend on the core size of the infusion filter.

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

ISO 8536-11:2004 *Infusion equipment for medical use—Part 11: Infusion filters for use with pressure infusion equipment* (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**.

JIS T 3219: 2005 may be applied until July 28 in 2014.

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 edition of the indicated year shall apply but the revisions (including amendments) made thereafter shall not apply.

JIS T 0307 : 2004 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

NOTE : Corresponding International Standard : **ISO 15223** *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied* (IDT)

JIS T 3211 : 2011 *Sterile infusion administration set*

NOTE : Corresponding International Standards : **ISO 8356-4** *Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed* and **ISO 8536-8** *Infusion equipment for medical use—Part 8: Infusion equipment for use with pressure infusion apparatus* (Overall evaluation: MOD)

ISO 594-2 : 1998 *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 2: Lock fittings*

3 Terms and definitions

For the purposes of this Standard, the following definitions apply.

3.1 purified water

“purified water” specified in Official Monographs of Japanese Pharmacopoeia (hereafter referred to as “JP”), or water at least equivalent thereto in quality

3.2 endotoxin test water

“water for injection” specified in Official Monographs of JP or water produced by the other methods, which does not react within the detection limit of lysate (LAL) reagent used for the endotoxin test

3.3 primary container

packaging directly covering the infusion filter to keep sterility of the infusion filter

The packaging is relevant to a so-called “inner bag” if a further secondary packaging is used. However, some may not keep sterility and a protective cap shall keep sterility inside of the infusion filter.

3.4 secondary container

packaging directly covering the primary packaging and generally containing multiple infusion filters with the primary packaging, for example, 50 sets

3.5 male and female conical fittings

a part capable of attachment and release of tools with a male and female tapers, and fitting (lock system)

3.6 protective cap

a cap for preventing direct exposure of the male and female conical fittings to ambient air

3.7 infusion filter

a filter removing particulate foreign matters, bacteria and fungi in the infusion

3.8 vent

a device expelling air in the container of infusion filter

3.9 bacterial challenge test

evaluation of bacterial capturing performance of the infusion filter by infusion of a test solution containing an indicative bacterium from a primary inlet of the infusion filter and culture of a test solution discharged from the secondary outlet to confirm pore size of the infusion filter from the size of indicative bacterium