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Sterile winged intravenous devices

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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 3222 : 2005** is replaced with this Standard.

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Sterile winged intravenous devices

Introduction

This Japanese Industrial Standard is the standard which is revised so that the contents such as terms and constitution of documents are altered for the convenience of users in the review of **JIS T 3222** established in 2005.

1 Scope

This Standard specifies the single-use sterile winged intravenous devices (hereafter referred to as “winged intravenous devices”).

Moreover, **JIS T 3222 : 2005** may be applied until July 28th, 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 G 4305 : 2005 *Cold-rolled stainless steel plate, sheet and strip*

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

JIS T 0993-1 : 2005 *Biological evaluation of medical devices—Part 1: Evaluation and testing*

JIS T 3210 : 2011 *Sterile injection syringes*

ISO 594-1 : 1986 *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 1 : General requirements*

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

ISO 3696 : 1987 *Water for analytical laboratory use—Specification and test methods*

ISO 6009 : 1992 *Hypodermic needles for single use—Colour coding for identification*

ISO 9626 : 1991 *Stainless steel needle tubing for the manufacture of medical devices and Amendment 1 : 2001*

3 Terms and definitions

For the purposes of this Standard, the following terms and definitions of main terms apply:

3.1 nominal outside diameter

dimension of the outside diameter of needle tube indicated on the encapsulation or container of winged intravenous devices

3.2 nominal length

dimension of the length of needle tube indicated on the encapsulation or container of winged intravenous devices

3.3 purified water

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

3.4 endotoxin test water

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

3.5 primary container

packaging to directly cover the winged intravenous devices, used for maintaining the sterility of winged intravenous devices

Furthermore, if the secondary container is performed on this, it corresponds to an “inner bag”. However, some containers do not maintain the sterility of devices. In such case, the sterility of the inside of the winged intravenous device shall be maintained using a protective cap.

3.6 secondary container

packaging to directly cover the primary container, in which the multiple winged intravenous devices, for example 50 devices, packaged primarily are contained

3.7 needle tube

sharp tube to puncture the vessel and administer the medication

3.8 wing

alary part to fix the needle tube

3.9 tubing

tube to lead the medication into the body

3.10 female conical fitting

part whereby connection and removal between devices can be performed

4 Configuration and name of each part

Winged intravenous device mainly consists of needle tube, wing, tubing and female conical fitting. Example of general winged intravenous device is illustrated in figure 1.