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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 18671-2009

Replacing GB 18671-2002

Intravenous needles for single use

一次性使用静脉输液针

Issued on: May 6, 2009 **Implemented on: March 1, 2010**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine;
Standardization Administration of the PRC

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Foreword

All technical content of this Standard is mandatory. This Standard replaces GB 18671-2002 "Intravenous infusion needles for single use." The main differences between this Standard and GB 18671-2002 are as follows: - the applicable scope was expanded to infusion needles for. gravity feed- type infusion sets, infusion sets used with pressure infusion equipment, and transfusion sets; the corresponding requirements were added; - added infusion needle with

0.36 mm needle tube specification and corresponding requirements; - changed product mark to specification mark; - made connection base requirements mandatory; - re-categorized the requirement relating to inner diameter for quick evaluation of needle tube openness to flow; it is now a requirement in informational Annex form for further evaluation of needle tube and needle tip quality; eliminated the qualitative needle tip puncture force test methods; - changed pH test to titrimetric method; - eliminated the ethylene oxide residue quantity requirement for infusion needles sterilized with ethylene oxide; added a requirement that packaging make use of dialytic materials; - revised mark and packaging requirements; - eliminated the exit-factory inspection. Annex A and Annex B of this Standard are normative. Annex C and Annex D are informative. This Standard was proposed by China State Food and Drug Administration. This Standard shall be under the jurisdiction of China National Technical Committee on Standardization of Medical Infusion Devices. Drafting organizations of this Standard. Zhejiang Kangdelai Medical Apparatus

Stock Co., Ltd., Jinan Quality Supervision and Inspection Centre for Medical Devices of China State Food and Drug Administration. Main drafters of this Standard. Zhang Honghui, Song Jinzi, Wu Ping, Jia Fei. This Standard replaces the following previous version. - GB 18671-2002.

There are two main forms in which intravenous infusion needles are supplied. One is supplied to hospitals together with infusion and transfusion sets.; the other is supplied to hospitals as independent commercial products. The first one accounts for the great majority of such needles in China. The sterility, packaging, and labelling requirements of this Standard do not apply to intravenous infusion needles supplied together with infusion and transfusion sets. To meet different clinical needs, this Standard does not limit combinations of needle tube outer diameter and length. However, in view of the need to provide identification for product sales and clinical use, this Standard requires labelling of needle tube length, tube wall type, and needle tip type in addition to labelling of needle tube outer diameter. As a transitional measure, GB 18671-2002 classified the G/T 1962 requirement on inner conical fittings as a suggested requirement. Seeing as many enterprises have gradually adopted semi-rigid 6% inner conical fittings, this version has reclassified the requirement as mandatory. Intravenous needles for single use

1 Scope

China's mandatory standard for single-use intravenous infusion needles - the winged needle and its tubing at the patient end of an infusion set, one of the highest-volume medical devices made anywhere and one where a defect is delivered directly into a vein. The standard specifies the requirements for single-use intravenous infusion needles, together with the corresponding test methods, the inspection rules and the provisions on marking, packaging, transport and storage. The requirements are those that decide whether the device is safe and whether it works. On safety: the sterility and the freedom from pyrogens, the biological evaluation of everything that touches blood, the limits on the substances extractable from the plastics and on the particulate matter that can be washed out of the flow path, and the acidity, alkalinity and metal content of the extract - because whatever comes off the device goes into the circulation. On performance: the sharpness and the geometry of the needle point, which is what a patient feels; the strength of the bond between the needle and its hub and between the hub and the tubing, since a separation under pressure is a bleed or an air embolism; the freedom from leakage under positive and negative pressure; the flow rate; and the transparency of the tubing, which is how a nurse sees the flashback that confirms the vein has been entered. The packaging is part of the product here rather than an accessory: it holds the sterile barrier, and the standard sets what it must be and what must be printed on it, including the single-use symbol and the expiry. Issued on 6 May 2009 and in force since 1 March 2010, it replaces GB 18671-2002.

This Standard specifies requirements for single-use intravenous infusion needles

(hereinafter referred to as "infusion needles") of which the nominal outer diameter is

0.36 mm ~

1.2 mm to ensure adaptability to gravity feed-type infusion sets, infusion sets used with pressure infusion equipment, and transfusion sets. This Standard provides a guide to the properties and quality norms for the materials used in infusion needles. Clause 3 to 8.1, and

8.3 of Clause 8 of this Standard give quality norms for infusion needles supplied with infusion and transfusion sets.

2 Normative references

The following standards contain the provisions which, through reference in this Standard, constitute the provisions of this Standard. For dated references, subsequent amendments (excluding corrections) or revisions do not apply to this Standard. However, the parties who enter into agreement based on this Standard are encouraged to investigate whether the latest versions of these documents are applicable. For undated reference documents, the latest versions apply to this Standard.

GB/T 1962.1 Conical fittings with a 6% (Luer) taper for syringes, needles and other medical equipment - Part

3 Structure and naming

Figure 1 shows the structure, names of parts, and needle tube length (L) of a typical infusion needle.

4 Examples of marking

4.1 Infusion needle specification mark is presented in terms of needle tube nominal diameter, nominal length, tube wall type, and angle (alpha) of first bevel of needle tip. The outer diameter and length are expressed in "mm".

4.2 For an infusion needle that is compliant with This Standard, that has a needle tube nominal outer diameter of

0.7 mm, a nominal length (L) of 30 mm, and a tube wall type of thin wall, and that has a needle tip first bevel angle that is a long bevel angle, the specification mark is.

5 Materials

The needle tubing used to manufacture infusion needles shall comply with the requirements of GB 18457.

6 Physical requirements

6.1 Color labelling The color of the needle handle and/or sheath of an infusion needle shall be used to label the nominal outer diameter of the needle tube. The color shall comply with the requirements of YY/T 0296.

6.3 Firmness of connections

6.3.1 When subject to 20 N axial static pulling force for 10 continuous seconds, the connection between the infusion needle handle and the needle tube shall not break or become loose.

6.4 Leakage The inner cavity of the infusion needle shall have a good seal. It shall not leak when tested in accordance with Clause A.2. Infusion needles used together with infusions sets used with pressure infusion equipment shall comply with the requirements in

6.3 of YY0286.4-2006.

6.5 Flow When tested in accordance with Clause A.3, the outflow of water under 20 kPa pressure shall be no lower than what is specified in Table 1.

6.6 Length of needle tube When the nominal length of the needle tube is less than or equal to 15 mm, the needle tube length (L in Figure 1) shall be the nominal value ±

1.0 mm. When the nominal length is greater than 15 mm, the needle tube length shall be the nominal value +

6.8 Lubricant If a needle tube is coated with a lubricant, examine the needle with normal or corrected vision. There shall be no visible lubricant accumulations on the outer surface of the needle tube.

6.9 Connecting base The conical fitting of the connecting base shall comply with the requirements of GB/T 1962.1 or GB/T 1962.2. The connecting base of an infusion needle used in an infusion set used with pressure infusion equipment shall employ a lock fitting.

6.11 Flexible tube The flexible tube of the infusion needle shall be soft, transparent, bright and clean, and free of obvious mechanical impurities, foreign matter, and kinks. It shall be transparent enough to allow observation of bubbles and drawn blood.

7 Chemical requirements

7.1 Reducing substances When testing in accordance with Clause B.2, the difference between volumes of potassium permanganate solution [c(KMnO4) =

0.002 mol/L] consumed by the test solution and by the blank solutions shall not exceed

7.2 Metal ions When conducting an assay according to the atomic absorption spectroscopy