NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB 8368-2018

Infusion sets for single use -- Gravity feed

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Foreword

The full technical content of this Standard is mandatory.

This Standard is drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard replaces GB 8368-2005 "Infusion sets for single use, gravity feed". Compared with GB 8368-2005, in addition to editorial changes, the main technical changes of this Standard are as follows:

- CHANGE the note in Tubing to the text (see 6.6; 6.6 of the 2005 edition);
- Delete the limit on the colour of the flow regulator (6.9 of the 2005 edition);
- Modify the position requirement of injection site to mandatory requirement and add a note (see 6.11; 6.11 of the 2005 edition);
- Modify the requirement of male conical fitting to mandatory requirement (see 6.12; 6.12 of the 2005 edition);
- Modify the requirements for reducing matter and the method of presentation of test method (see 7.1 and B.2; 7.1 and B.2 of the 2005 edition);
- In Labelling, add a requirement that the presence of substances of interest can be indicated by using symbol 2725 of ISO 7000 (see notes to 9.1 and 9.2);

- ADD packaging requirement (see 10.3);

- ADD disposal requirement (see Clause 11);

- Modify particulate contamination index and its test method (see A.1; A.1 of the 2005 edition);

- Modify tests for leakage (see A.2; A.2 of the 2005 edition).

This Standard uses the redraft law to modify and adopt ISO 8536-4:2010 "Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed".

There are technical differences between this Standard and ISO 8536-4:2010. The clauses involved in these differences have been marked by a vertical single line (|) at the blank of the outer margin. Annex E gives a list of the corresponding technical differences and their causes.

This Standard incorporates the amendment contents of ISO 8356-4:2010/Amd.1:2013. The clause-subclause involved in these amendment contents has been marked by vertical double line (||) at the blank of the outer margin.

This Standard also makes the following editorial changes:

- ADD the informative Annex D, to provide guidelines for the design and implementation of infusion sets in China;

- ADD the informative Annex E, giving a list of corresponding technical differences and their causes compared to ISO 8536-4:2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority of this document shall not be held responsible for identifying any or all such patent rights.

This Standard was proposed by and shall be under the jurisdiction of China Food and Drug Administration.

Main drafting organizations of this Standard: Shandong Quality Inspection Center for Medical Devices, Shandong Weigao Group Medical Polymer Co.,

Ltd., Shinva Ande Healthcare Apparatus Co., Ltd., Shanghai Kindly Enterprise Development Group Co., Ltd., Jiangxi Hongda Medical Equipment Group Ltd., Tianjin Hanaco Medical Co., Ltd., Jiangxi Sanxin Medtec Co., Ltd., Chengdu Xinjin Shifeng Medical Apparatus & Instrument Co., Ltd., Shandong Zhongbaokang Medical Implements Co., Ltd.

Main drafters of this Standard: Wan Min, Wang Yi, Li Songhua, Pan Huaxian, Gao Yicen, Wang Haiyin, Hou Li, Zhu Li, Liu Xiaohong, Tian Xinglong, Zhang Min.

The previous editions of the standard replaced by this Standard were released as follows:

- GB 8368-1987, GB 8368-1993, GB 8368-1998, GB 8368-2005.

Infusion sets for single use - Gravity feed

1 Scope

This Standard specifies the designation, materials, physical, chemical, and biological requirements for single-use gravity feed infusion sets.

This Standard applies to single-use gravity feed infusion sets for use with infusion containers and intravenous equipment.

2 Normative references

The following documents are indispensable for the application of this document. For the dated references, only the editions with the dates indicated are applicable to this document. For the undated references, the latest edition (including all the amendments) are applicable to this document.

GB/T 1962.2 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings (GB/T 1962.2-2001, ISO 594-2:1998, IDT)

GB/T 6682 Water for analytical laboratory use - Specification and test methods (GB/T 6682-2008, ISO 3696:1987, MOD)

GB/T 14233.1-2008 Test methods for infusion, transfusion, injection