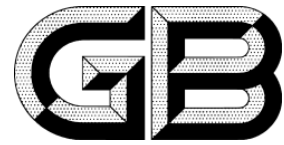


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**NATIONAL STANDARD OF THE  
PEOPLE'S REPUBLIC OF CHINA**

**GB/T 18457-2024**

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**Stainless steel needle tubing for the manufacture of medical  
devices - Requirements and test methods**  
**(English Translation)**

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## Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020

"Directives for standardization - Part 1.Rules for the structure and drafting of standardizing documents".

This document replaces GB/T 18457-2015 "Stainless steel needle tubing for the manufacture of medical devices". Compared with GB/T 18457-2015, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

- a) CHANGE the scope, ADD the size of 0.18 mm (34G) (see Chapter 1; Chapter 1 of the 2015 edition);
- b) ADD the terms and definitions (see Chapter 3);
- c) CHANGE the requirements for materials (see Chapter 4; Chapter 4 of the 2015 edition);
- d) ADD the size requirements for ultra-thin walls and very thin walls of some specifications (see Chapter 5);
- e) ADD the specific size requirements for the nominal outer diameter of 0.18 mm needle tubes (see Table 1);
- f) CHANGE the requirements for size marking (see 5.5; Chapter 5 of the 2015 edition);
- g) CHANGE the needle tube size and stiffness parameter table (see 5.7; Chapter 9 of the 2015 edition);
- h) CHANGE the relevant requirements for the preparation method of the test solution (see Appendix B; Appendix B of the 2015 edition);
- i) DELETE the "Test method for pH of needle tubes" (see Appendix C of the 2015 edition);

- j) CHANGE the test method and requirements for needle tube stiffness (see Appendix C; Appendix D of the 2015 edition);
- k) CHANGE the test method and requirements for needle tube toughness (see Appendix D; Appendix E of the 2015 edition);
- l) CHANGE the requirements for the needle tube corrosion resistance test report (see E.4; F.4 of the 2015 edition).

This document modifies and adopts ISO 9626.2016 "Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods".

Compared with ISO 9626.2016, this document has made the following structural adjustments.

- DELETE 5.7 of ISO 9626.2016, the subsequent article numbers have been moved forward;
- ADD the Appendix A;
- Appendix B corresponds to Appendix A of ISO 9626.2016;
- Appendix C corresponds to Appendix B of ISO 9626.2016;
- Appendix D corresponds to Appendix C of ISO 9626.2016;
- Appendix E corresponds to Appendix D of ISO 9626.2016;
- DELETE the Appendix E of ISO 9626.2016.

The technical differences between this document and ISO 9626.2016, as well as their reasons, are as follows.

- CHANGE the material requirements, to meet domestic technical conditions (see Chapter 4; Chapter 4 of ISO 9626.2016);
- DELETE the requirements of 5.7 "Sample size" in ISO 9626.2016, to avoid ambiguity with 5.1 General;
- USE the normative reference GB/T 6682 to replace ISO 3696 (see B.2.1), to adapt to China's national conditions;
- CHANGE the toughness requirements, to meet domestic technical requirements (see Appendix D; Appendix C of ISO 9626.2016).

This document has made the following editorial changes.

- DELETE the notes in Chapter 4 of ISO 9626:2016;
- ADD the "Stainless steel designations" (see Appendix A);
- DELETE the informative Appendix E of ISO 9626:2016 "Basic principles of needle tube stiffness test method".

Please note that some contents of this document may involve patents. The issuing agency of this document does not assume the responsibility for identifying patents.

This document was proposed by the State Food and Drug Administration.

This document shall be under the jurisdiction of the National Technical Committee for Standardization of Medical Syringes (Needles) (SAC/TC 95).

This standard replaces the standard previously issued as follows.

- It was first published in 2001 as GB 18457-2001; it was revised for the first time in 2015;
- This is the second revision.

## 1 Scope

This document specifies the requirements for stainless steel needle tubes (hereinafter referred to as needle tubes), which have designated metric sizes ranging from 0.18 mm (34G) to 3.4 mm (10G); describes the test methods.

## 2 Normative references

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, for dated references, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies to this document.

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

ISO 15510:2014 Stainless steels - Chemical composition