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

GB 10010-2009

Replacing GB/T 10010-2009

**Plasticized polyvinyl chloride tubing for medical uses
(English Translation)**

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document replaces GB/T 10010-2009 "Medical Flexible Polyvinyl Chloride Pipes". Compared with GB/T 10010-2009, the only changes are structural adjustments.

Aside from editorial changes, the main technical changes are as follows.

- The scope has been changed (see Chapter 1, Chapter 1 of the 2009 edition);
- Added terms and definitions (see Chapter 3);
- Added categories (see Chapter 4);
- The physical and mechanical performance specifications have been changed (see 5.3, 3.3 in the 2009 edition);
- The heavy metal indicators and test methods have been revised (see 5.4.2, 6.5.3, and 3.4.2 and 4.4.3 in the 2009 version);
- Added color indicators and test methods (see 5.4.7, 6.5.8);
- The biological performance indicators and test methods have been revised (see 5.5, 6.6, and 3.5 and 4.5 in the 2009 edition);
- The dimensional deviation test method has been changed (see 6.2, 4.1 in the 2009 version);
- The method for testing compression set has been modified (see 6.4.2, 4.3.3 in the 2009 version);

---The Shore hardness test method has been modified (see 6.4.3, 4.3.4 in the 2009 version);

---The classification of tests has been changed (see 7.1, 5.1 in the 2009 edition);

---The logo has been changed (see 8.1, 8.2, and 6.1 in the 2009 edition).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the China National Light Industry Council.

This document is under the jurisdiction of the National Technical Committee on Standardization of Plastic Products (SAC/TC48).

1 Scope

This document specifies the classification, requirements, inspection rules, marking, packaging, transportation, and storage of medical flexible polyvinyl chloride tubing (hereinafter referred to as tubing).

The document describes the corresponding experimental methods.

This document applies to applications using polyvinyl chloride resin as the main raw material in medical-related fields, used for conveying fluid media-gases and liquids.

(e.g., blood, medicine, nutrient solution, excrement, etc.), production, inspection, and... of PVC pipes with a Shore (A) hardness in the range of 40-90.

Sale.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB/T 1040.2-2022 Determination of tensile properties of plastics - Part 2: Test conditions for molded and extruded plastics
GB/T 2035 Plastics Terminology
GB/T 2411 Determination of indentation hardness (Shore hardness) of plastics and hard rubber using a hardness tester
GB/T 4615 Determination of Residual Vinyl Chloride Monomer in Polyvinyl Chloride by Gas Chromatography
GB/T 14233.1-2022 Medical infusion, transfusion and injection equipment test methods - Part 1: Chemical analysis methods
GB/T 16886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing in

the risk management process YY/T 0466.1 Symbols for medical devices used to provide information to manufacturers - Part 1: General requirements Pharmacopoeia of the People's Republic of China, Part IV

3 Terms and Definitions

The terms and definitions defined in GB/T 2035 apply to this document.

4 Classification

Pipes are classified into three categories based on their hardness.

- Class I. Shore (A) hardness greater than or equal to 40 and less than 63;
- Class II. Shore (A) hardness greater than or equal to 63 and less than 73;
- Class III. Shore (A) hardness greater than or equal to 73 and less than or equal to 90.

5.1 Dimensional Deviation

The limit deviations of pipe specifications and dimensions shall conform to the provisions of Table 1.