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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0489-2023

Replacing YY/T 0489-2004

Sterile drainage catheters and accessory devices for single use

一次性使用无菌引流导管及辅助器械

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document replaces YY/T 0489-2004 "Single-use sterile drainage catheters and

auxiliary devices" and is consistent with YY/T 0489-2004.

In addition to structural adjustments and editorial changes, the main technical changes are as follows.

- a) Added "risk management" requirements (see 5.1);
- b) Changed "radio detectability" to "detectability" and modified the corresponding technical contents (see 5.3, 4.4 of the 2004 edition);
- c) Added "Appearance" requirements (see 5.4);
- d) Added "size identification" requirements (see 5.5);
- e) Added "connectors" requirements (see 5.6);
- f) Added the "Magnetic Resonance Imaging (MRI) Compatibility" requirement (see 5.7);
- g) The requirement for "sterility" has been changed (see 5.8, 4.8 of the 2004 edition);
- h) Changed the requirements for "ethylene oxide residue" (see 5.9, 4.8 of the 2004 edition);
- i) The requirements for "kink stability" have been changed (see 6.1, 4.1 of the 2004 edition);
- j) "Corrosion test" was changed to "corrosion resistance", and the corresponding technical content was changed (see 6.2, 4.9 of the 2004 edition);
- k) Changed "breaking force" to "peak tensile force" and changed the corresponding technical content (see 6.4, 4.3 of the 2004 edition);
- l) Added "flow rate" requirements (see 6.6);
- m) Added "fixing strength" requirements (see 6.7);
- n) Added the "balloon reliability" requirement (see 6.8);
- o) Added the requirement of "integrity and volume maintenance of drainage catheter filling lumen" (see 6.9);
- p) Added the requirement of "tensile strength of inflated balloon" (see 6.10);
- q) Changed "marking" and "packaging" to "information provided by the manufacturer" and changed the corresponding technical content (see Chapter 7, 2004 5 and 6 of the 2002 edition);
- r) Added the normative appendix "Corrosion resistance test method" (see Appendix B);
- s) Change "Test method for resistance to deformation of drainage system or any component" to "Test method for resistance to deformation by attraction", and change the corresponding technical Technical content (see Appendix C, Appendix A of the 2004 edition);
- t) Added the normative appendix "Test method for determining the peak tensile force of the

connection" (see Appendix D);

u) Added the normative appendix "Test method for determining the peak tensile force of drainage catheters" (see Appendix E);

v) Added the normative appendix "Drainage catheter flow measurement test method" (see Appendix G);

w) Added the normative appendix "Balloon reliability test method" (see Appendix I);

x) Added the normative appendix "Test methods for leakage and/or function and/or balloon deflation (Drainage with compliant balloon)" catheter" (see Appendix J);

y) Added the normative appendix "Test method for determining balloon size and retraction reliability (drainage catheters with non-compliant balloons)" (See Appendix K);

z) Added the normative appendix "Test method for determining the tensile strength of balloon" (see Appendix L);

aa) Added the normative appendix "Test method for leakage resistance during suction or vacuum process" (see Appendix M).

This document is modified to adopt ISO 20697:2018 "Single-use sterile drainage catheters and auxiliary devices".

The technical differences between this document and ISO 20697:2018 and their reasons are as follows.

a) Added the definitions of "compliant balloon" (see 3.18) and "non-compliant balloon" (see 3.19) to improve the applicability of this document;

b) Changed the relevant requirements for clinical research in "Risk Management" (see 5.1) to improve the applicability of this document in light of my country's national conditions;

c) The requirements for "sterility" (see 5.8) have been changed to improve the applicability of this document in light of my country's national conditions;

d) Added the requirement of "ethylene oxide residue" (see 5.9) to protect the health of medical staff and patients.

1 Scope

This document specifies the requirements for single-use sterile drainage catheters, wound and effusion drainage systems, surgical drainage catheters and related components.

A catheter is placed surgically or percutaneously in a body cavity or wound to drain fluid or air to the outside of the body.

The drainage catheter is left for natural drainage or connected to a suction source (to accelerate tissue granulation).

This document does not apply to.

---Suction catheter;

---Tracheal tube;

---Urinary catheter;

Note 1: See YY/T 0325.

---Ureteral stents, biliary stents and other stents;

Note 2: For requirements on brackets, see ISO 14630 and ASTM F1828-97.

--- Drainage tubes inserted percutaneously into the digestive tract using gastrostomy;

---Axonal catheters for removal of cerebrospinal fluid;

Note 3: See ISO 20698.

---Intestinal catheters used to remove solutions or substances from the gastrointestinal tract;

Note 4: See ISO 20695.

---coating.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

GB/T 14233.1 Inspection methods for medical infusion, blood transfusion and injection equipment Part 1: Chemical analysis methods GB/T 16886.1 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process (GB/T 16886.1-2022, ISO 10993-1:2018, IDT) YY/T 0615.1 Requirements for labeling "sterile" medical devices Part 1: Requirements for terminally sterilized medical devices YY/T 0916.1 Small-bore connectors for medical liquids and gases Part 1: General requirements (YY/T 0916.1-2021, ISO 80369-1:2018, IDT)

3 Terms and definitions

The following terms and definitions apply to this document.

Accessory device

Access and/or drainage devices [e.g., collection devices (3.3)] for use with drainage