ICS 11.080.01
CCS C47

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0970-2023

Replacing YY 0970-2013

Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Characterization of a sterilization process for medical devices

医疗保健产品灭菌 一次性使用动物源性医疗器械的液体化学灭菌剂 医疗器械灭菌过程的特征

Issued on: March 14, 2023 **Implemented on: May 1, 2026**

Issued by: National Medical Products Administration

Table of Contents

Foreword

The entire technical content of this document is mandatory: 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 0970-2013 "Sterilization of single-use medical devices containing animal source materials Recognition and Routine Controls: Compared with YY 0970-2013, the main differences are as follows:

--- Changed the name of the standard;

--- Changed the scope of the standard;

---Added GB/T 16886:1, GB/T 16886:17, GB/T:19973:1, General Rules of Part Four of Pharmacopoeia of the People's Republic of China 1101 Sterility test method, YY/T 0567 (all parts) and other normative references (see Chapter 2), delete ISO 9001: 1994, ISO 9002:1994, ISO 11138-1:1994, ISO 11737-1:1995, ISO 13408-1:1998 and other normative references Use documents (see Chapter 2 of the:2013 edition);

--- Changed terms and definitions [Added "maintenance time" (see 3:5), "inactivation curve" (see 3:6), "installation qualification" (see 3:8), "operating Identification" (see 3:11), "parametric release" (see 3:12), "product family" (see 3:14), "reference microorganism" (see 3:15), "re-qualification "Determined" (see 3:16), "Requirements" (see 3:17), "Sterile Barrier System" (see 3:19), "Sterilization Assurance Level" (see 3:21), "Substitute Product" (see 3:24), "sterility test" (see 3:25), "organization" (see 3:26), changed "batch" (see 3:1,

3:1 of the:2013 edition), "Bioburden" (see 3:2, 3:2 of the:2013 edition), "D value" (see 3:4, 3:5 of the:2013 edition), "contaminated carrier" (see 3:7, 3:8 of the:2013 edition), "liquid chemical sterilant" (see 3:9, 3:9 of the:2013 edition), "inactivation" (see 3:10,:2013 edition 3:7), "performance appraisal" (see 3:13, 3:11 of the:2013 edition), "confirmation" (see 3:27, 3:20 of the:2013 edition), deleted "test Operation" (see 3:4 of the:2013 edition), "action time" (see 3:6 of the:2013 edition), "medical device" (see 3:4 of the:2013 edition 3:10), "count before sterilization" (see 3:12 of the:2013 edition), "product suitability" (see 3:13 of the:2013 edition), "process development" (see 3:14 of the:2013 edition), "reconfirmation" (see 3:15 of the:2013 edition), "viable count" (see:2013 edition 3:21)];

--- Added "Sterilant Characteristics" (see Chapter 5), "Process and Equipment Characteristics" (see Chapter 6), "Product Definition" (see Chapter 7), "Process Definition" (see Chapter 8), "Maintaining the Sterilization Process Effectiveness" (see Chapter 12), "YY/T 0567 and ISO 13408 The degree of consistency between the various parts of the standard" (see Appendix A), "Determination of the kill rate of the sterilization process" (see Appendix C), "Microbial Killing effect, process definition and microbial performance identification flow chart" (see Appendix D) and other technical contents;

---Changed the chapter "General" (see Chapter 4, Chapter 4 of the:2013 edition);

---Changed the chapter "Confirmation" (see Chapter 9, Chapter 5 of the:2013 edition);

---Changed the chapter "General Monitoring and Control" (see Chapter 10, Chapter 6 of the:2013 edition);

---Changed the chapter "Product Sterilization Release" (see Chapter 11, Chapter 7 of the:2013 edition);

--- Changed the "Application Guidelines" (see Appendix B, Appendix A of the:2013 edition): This document is modified to adopt ISO 14160:2020 "Liquid chemistry for the sterilization of single-use medical devices of animal origin for the sterilization of healthcare products": Requirements for the Characterization, Development, Validation and Routine Control of Sterilization Processes for Medical Devices": The technical differences between this document and ISO 14160:2020 and their reasons are as follows:

--- Regarding the normative reference documents, this standard has made adjustments with technical differences to adapt to the technical conditions of our country and the adjustment situation The situation is reflected in Chapter 2 "Normative References", and the specific adjustments are as follows: - Added "Pharmacopoeia of the People's Republic of China" General Chapter 1101 Sterility Test Method as a normative reference document, 10:

6 Involving sterility testing requirements; - Replace ISO 10993-1 with GB/T 16886:1, which is equivalent to the international standard (see Chapter 7); - Replace ISO 10993-17 with GB/T 16886:17, which is equivalent to the international standard (see Chapter 1, Chapter 7); - Replaced ISO 11737-1 with GB/T:19973:1, which is equivalent to the international

standard (see Chapter 7, Chapter 8, Chapter 9, Chapter Chapter 10, Appendix B); - Replace ISO 13408 (all parts) with YY/T 0567 (all parts), the degree of consistency between the parts of the two standards See Appendix A:

--- The definition of the term "medical device" has been deleted to avoid conflicts with the definition of "medical device" in my country's regulations:

1 Scope

YY 0970 governs the liquid chemical sterilization of single-use medical devices made from animal tissue, the graft materials, heart valves and surgical meshes derived from bovine, porcine or equine sources. These devices cannot be steam sterilized without destroying them, so they are treated with a liquid chemical agent instead, and the standard sets out how such a process is characterised: how the agent, the contact conditions and the load are defined, how sterility assurance is demonstrated, and how the process is validated and kept under control. Animal-derived devices also carry a viral and prion risk that ordinary sterilization arguments do not address. Being a YY standard without the /T suffix, compliance is compulsory in China. The 2023 edition replaces YY 0970-2013 and takes effect in May 2026.

This document specifies the requirements for liquid chemical sterilants for the sterilization of single-use medical devices wholly or partly derived from animal materials: characteristics, and requirements for sterilization development, validation, process control and monitoring: This document is applicable to the risk control of bacterial and fungal contamination in the liquid chemical sterilization process, the risks associated with other microorganisms can be used Other methods for evaluation (see Note 1): This document does not apply to:

---Materials of human origin;

---Confirmation of virus and transmissible spongiform encephalopathy (TSE) inactivation (see Note 2 and Note 3);

--- Confirmation of inactivation or elimination of protozoa and parasites;

--- Treatment process to reduce bioburden during production (see Note 4);

--- Test and evaluation of the suitability of the sterilization process for the use of medical devices (see Note 5);

---Development of sterilant residue levels in medical devices (see Note 6):

Note 1: According to the description in YY/T 0771:1, it is very important to prioritize the application of risk management principles for medical devices of animal origin: ISO 18362 provides the basis for Microbial risk control in the production process of cell-based healthcare products: NOTE 2: Liquid chemical sterilants are commonly used to sterilize

animal tissues in medical devices and may be effective against transmissible spongiform encephalopathy (TSE) such as bovine spongiform encephalopathy (BSE) or inactivation of the causative agent of scrapie did not work: It is therefore not appropriate to use the methods of this document to confirm the inactivation of this class of infectious agents: and See YY/T 0771:2 for risk control related to the source, collection and disposal of animal materials:

Note 3: See YY/T 0771:3 for confirmation of inactivation and/or elimination of viruses and TSE pathogenic factors:

Note 4: The production process of medical devices of animal origin often includes exposure to chemical agents, which can significantly reduce the bioburden of medical devices: in the production process Afterwards, the medical device is exposed to a specific sterilization process: Note 5 to entry: Such tests are a key component in the design and development of medical devices:

Note 6: GB/T 16886:17 specifies the method for establishing acceptable limits of sterilant residues:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document: GB/T 16886:

1 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process (GB/T 16886:1- 2011, ISO 10993-1:2009, IDT) GB/T 16886:

17 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (GB/T 16886:17- 2005,

ISO 10993-17:2002, IDT) GB/T:19973:

1 Microbiological methods for sterilization of medical devices Part 1: Determination of the total number of microorganisms on the product (GB/T:19973:1-2015, ISO 11737-1:2006, IDT)