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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0503-2023

Replacing YY 0503-2016

Ethylene oxide sterilizer

环氧乙烷灭菌器

Issued on: June 20, 2023 **Implemented on: July 1, 2025**

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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 YY 0503-2016 "Ethylene Oxide Sterilizer". Compared with YY 0503-2016, except for structural adjustments and editorial changes, In addition, the main technical changes are as follows:

---Changed the description of the standard scope (see Chapter 1, Chapter 1 of the.2016 edition);

---Deleted the terms "sterilizer", "sterilizing agent", "sterilization temperature", "sterilization pressure" and "sterilization humidity" (see 3.1, 3.4,.2016 version) 3.5, 3.6, 3.7), adding the terms "ethylene oxide aerosol can" and "ethylene oxide gas cylinder" (see 3.9, 3.10);

---Mark removed (see

4.2 of the.2016 version);

---Deleted normal working conditions (see

5.1 of the.2016 version);

---Changed the appearance requirements (see 5.1,

5.2 of the.2016 version);

---Changed the size requirements (see 5.2,

5.3 of the.2016 version);

---Changed the requirements for materials and structures (see 5.3.1,

5.4.1 of the.2016 edition);

1 Scope

YY 0503 is the mandatory Chinese standard for the ethylene oxide sterilizer, the equipment that sterilises heat-sensitive medical devices with a toxic, flammable and carcinogenic gas. That combination is why the standard exists in mandatory form: the requirements cover not only whether the load comes out sterile but whether the gas stays inside the machine, how the chamber is sealed and monitored, how residues are removed before the load is handled, and what the alarms and interlocks do when something fails. Ethylene oxide remains irreplaceable for a large share of single-use devices, so these machines run continuously in Chinese device plants and hospital sterilisation departments. The 2023 edition replaces YY 0503-2016 and took effect in July 2025. This is the text a manufacturer certifies against and an inspector applies.

This document specifies the classification and requirements of ethylene oxide sterilizers (hereinafter referred to as sterilizers) and describes the corresponding test methods. This document applies to products that use ethylene oxide gas (whether pure ethylene oxide gas or a mixture with other gases) as a sterilizing agent. Automatically controlled sterilizer. Sterilizers can be used for industrial production sterilization of medical devices and sterilization in medical institutions. This document does not apply to sterilization methods that directly inject ethylene oxide or mixtures containing ethylene oxide into packaging or flexible cavities. equipment. This document does not stipulate the pressure vessel requirements for sterilizers, nor does it stipulate the treatment requirements for waste gas, waste water and other waste generated during ethylene oxide sterilization. Sum the ethylene oxide residues.

Note. If the sterilizer box meets the definition of a pressure vessel in special equipment, the sterilizer needs to meet the requirements of the corresponding regulations on pressure vessels.

2 Normative reference documents

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

GB 4793.1 Safety requirements for electrical equipment for measurement, control and testing laboratories Part

3 Terms and definitions

The terms and definitions defined in GB/T.19971, GB/T 18281.1 and the following apply to

this document.

3.1 box sterilizercase The equipment part of the sterilizer used to load sterilized items, including the sterilization chamber.

3.2 sterilizerchamber An enclosed space for loading sterilized items.

4 Paper bag requirements and test methods

YY/T 0698.5 Packaging materials for terminally sterilized medical devices Part

5.Sealable combination bags composed of breathable materials and plastic films and membrane requirements and test methods