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

YY/T 0679-2025

Replacing YY/T 0679-2016

Steam and formaldehyde sterilizers

蒸汽甲醛灭菌器

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Foreword

This document is in accordance with GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting is scheduled. This document replaces YY/T 0679-2016 "Medical Low-Temperature Steam Formaldehyde Sterilizer". Compared with YY/T 0679-2016, the main differences are in the structural design. Aside from integration and editorial changes, the main technical changes are as follows:

- The scope has been changed (see Chapter 1, Chapter 1 of the.2015 edition);
- Terminology and definitions have been changed (see Chapter 3, Chapter 3 of the.2016 edition);
- Changes have been made to the type, marking, and requirements for sterilizing agents (see Chapter 4, Chapter 4 of the.2016 edition);
- The requirements for the test connector have been changed (see 5.1.4, version
- The requirements for pressure measurement and display devices have been changed (see 5.3.4,.2016 version 5.3.4);
- The requirements for sterilization cycles and automated control have been changed (see 5.4.2,.2016 version 5.4.2);
- The physical parameter requirements have been changed (see 5.5.1, version
- Added requirements for the supply of sterilizing agents (see 5.5.2);
- Noise requirements have been changed (see 5.8,.2016 version 5.8);
- The environmental testing requirement has been removed (see 5.11 in the.2016 edition);

---The test methods for doors and interlocking devices have been modified (see 6.1.2,.2016 version of 6.1.2);

1 Scope

YY/T 0679 is the product standard for the low-temperature steam and formaldehyde steriliser, used on heat-sensitive medical items that cannot survive an autoclave. It specifies the types and the marking requirements for steam formaldehyde sterilisers and describes the corresponding test methods, and it applies to sterilisers that use a steam and formaldehyde mixture on heat-sensitive items. LTSF sits between steam and ethylene oxide in the hospital sterilisation toolkit, with its own problem: residual formaldehyde on the load has to be driven off before the item reaches a patient, so the process and its verification are inseparable. It takes effect on 1 January 2027. For a manufacturer or an importer of LTSF sterilisers for the Chinese market, this is the governing product standard.

This document specifies the types and markings of steam formaldehyde sterilizers (hereinafter referred to as sterilizers) and describes the corresponding test methods. This document applies to sterilizers that use a mixture of steam and formaldehyde gas to sterilize heat-sensitive medical items.

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 1914 Chemical Analysis Filter Paper

GB/T 3768 Acoustic pressure method for determining the sound power level and sound energy level of a noise source using a simplified measurement method based on the envelope above the reflecting surface. Easy Method

GB/T 3785 (all parts) Electroacoustic sound level meters

GB 4793.1 Safety requirements for electrical equipment for measuring, control and laboratory use - Part

3 Terms and Definitions

The terms and definitions defined in GB 18278.1 and GB/T.19971, as well as the following terms and definitions, apply to this document.

3.1 Access control tool accessdevice Keys, passwords, or tools that can only be used by authorized persons.

3.2 Ventilation In one or more stages of the sterilization process, formaldehyde and its reaction products are desorbed from the sterilization load to a predetermined level under specific conditions. The process.

5 Biological indicators for low-temperature steam formaldehyde sterilization

GB/T 19633 (all parts) Terminally sterilized medical device packaging GB/T.19971-2015 Terminology for Sterilization of Medical and Health Products

GB/T 30121 Industrial platinum resistance thermometers and platinum temperature sensing elements

YY/T 0883 Technical Requirements for Process Challenge Apparatus and Indicator Systems for Vapor Permeability Testing