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

YY 1275-2016

Dry heat (heated air) sterilizers

热空气型干热灭菌器

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Foreword

This standard is drafted in accordance with the rules given in GB/T 1.1-2009. The technical content of this standard refers to ANSI/AAMIST50..2004 "dry heat (hot air) sterilizer" (English version), and ANSI / AAMIST50..2004 Consistency is non-equivalent. Please note that some of the contents of this document may involve patents. The issuer of this document does not assume responsibility for the identification of these patents. Appendix A of this standard is a normative appendix, Appendix B is an informative appendix. This standard is proposed by the State Food and Drug Administration. This standard by the National Disinfection Technology and Equipment Standardization Technical Committee (SAC/TC200) centralized. The drafting of this standard. Shandong Xinhua Medical Devices Co., Ltd., the State Food and Drug Administration Guangzhou medical equipment quality Supervision and inspection center, Lianyungang thousands of cherry Medical Equipment Co., Ltd. The main drafters of this standard. Wang Jianxin, Wang Hongmin, Hu Changming, Huang Xiulian, Zou Hongwu, Liu Zhenjian. Hot air type dry heat sterilizer

1 Scope

YY 1275 is the mandatory Chinese standard for dry heat sterilizers, the hot air ovens used for materials that steam would damage or cannot penetrate: glassware, oils, powders and some metal instruments. Dry heat kills by oxidation rather than by coagulation, which is far slower than steam and requires much higher temperatures, so the whole safety case rests on holding a uniform temperature for a validated time. The standard sets the requirements such equipment has to meet and the test methods that verify them, covering temperature uniformity through the chamber, the control and its accuracy, the timing of the cycle, and the recording that proves a load was actually processed. Being a YY standard without the /T suffix, compliance is compulsory in China.

This standard specifies the terms and definitions of hot air dry heat sterilizers, requirements, test methods, inspection rules and signs, packaging, use Brochures, transportation and storage. This standard applies to convective hot air as a sterilization medium for dry heat sterilizer (hereinafter referred to as sterilizer). The sterilizer is mainly used for experiments Indoor, nursing clinics, hospitals and other medical establishments

and their accessories. This standard does not apply to conductive or radiant dry heat sterilizers, does not specify the safety requirements related to the use of the risk range, does not require dry heat (Hot air) sterilization confirmation and routine control and dry heat pyrogen removal requirements.

2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article. For undated references, the latest edition (including all modifications) applies to this document.

GB/T 191 Packaging and Storage Icons (GB/T 191-2008, ISO 780..1997, MOD)

GB 4793.1 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1. General requirements (GB 4793.1-2007, IEC 61010-1..2001, IDT)

GB/T 4982 Vacuum technology - Quick release connector dimensions - Part 1. Clamping type [GB/T 4982-2003,

ISO 2861-1. 1974 (E), IDT] Environmental requirements and test methods for medical appliances GB/T 14710-2009

GB/T 18268 Electromagnetic compatibility requirements for electrical equipment for measurement, control and laboratory use (GB/T 18268-2000, IEC 61326- 1-1997, IDT)

YY/T 0466.1-2016 Symbols for medical devices for labeling, labeling and providing information on medical devices - Part 1. General purpose (ISO 15223-1..2007, IDT)

IEC 61010-2-040..2005 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040. Procedures for the treatment of medical equipment With the special requirements of sterilizers and cleaning sterilizers

(Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040. Particular requirements for sterilizers and washer-disin-

factors used to treat medical materials Disinfection technical specifications of the People's Republic of China Ministry of Health (2002 edition)

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Hot air heat dry sterilization dryHeat (heated air) sterilize Use convective hot air as a sterilization medium for sterilization.

3.2 Hold time holding time Sterilization chamber reference measurement point and the temperature of each part are kept in the sterilization temperature range.