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YY

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

YY 0731-2009

Replacing YY 91008-1999; YY 91009-1999

Large steam sterilizers - Manually controlled type

大型蒸汽灭菌器 手动控制型

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Foreword

5.1.2 This standard is recommended, the rest are mandatory. This standard also replace the YY 91008-1999 "pressure steam sterilizer horizontal circular

--- technical conditions", YY 91009-1999 "pressure Power steam sterilizer technical conditions

--- horizontal rectangle "and other two pharmaceutical industry standards. Since the implementation of this standard, the above two criteria Abolished. Appendix B of this standard is a normative appendix, Appendix A is an information appendix. This standard was proposed by the State Food and Drug Administration. This standard by the National Standardization Technical Committee disinfection technology and equipment (SAC/TC200) centralized. This standard was drafted. State Food and Drug Administration Guangzhou Medical Device Quality Supervision and Inspection Center, Lianyungang SENOH medical equipment Ltd., Shanghai Medical Nuclear Instrument Co., Ltd. China line. The main drafters of this standard. Li Jing, Huang Xiulian, Hu Changming, Liuzhen Jian, Zheng Hongqin. This standard by the National Standardization Technical Committee disinfection technology and equipment responsible for the interpretation. This standard replaces the standards previously issued as follows:

--- YY 91008-1999, YY 91009-1999.

--- GB 4027.3-1983, GB 4027.4-1983. Large steam sterilizers manual control type

1 Scope

YY 0731 is the mandatory Chinese standard for large manually controlled steam sterilizers, the autoclaves whose cycle is driven by an operator rather than by an automatic controller.

They remain in service across county and township hospitals in China, where they sterilise instruments and dressings for whole departments. Manual control is what shapes the standard: with no controller enforcing the cycle, the requirements have to cover the instrumentation the operator reads, the chamber and its pressure vessel safety, the steam quality, the air removal that determines whether steam actually reaches the load, and the recording that shows a cycle was completed. It replaces YY 91008-1999 and YY 91009-1999. Compliance is compulsory in China.

This standard specifies the terms and definitions manually controlled large steam sterilizer, type and basic parameters, requirements, test methods, inspection regulations Then, marking and instruction manual and packaging, transportation and storage. This standard applies to the rated working pressure of 0.25MPa or less, under the exhaust volume greater than 60L, manual control type steam off Bacteria filter (hereinafter referred to as sterilization). This standard does not apply to automatic control type large steam sterilizers, does not apply to vacuum type sterilizer.

2 Normative references

The following documents contain provisions which, through reference in this standard and become the standard terms. For dated references, subsequent Amendments (not including errata content) or revisions do not apply to this standard, however, encourage the parties to the agreement are based on research Whether the latest versions of these documents. For undated reference documents, the latest versions apply to this standard.

GB 150 steel pressure vessels

GB/T 191 Packaging - Pictorial signs (GB/T 191-2008, ISO 780.1997, MOD)

GB/T 1226 General Pressure Gauge

GB 4793.1 measurement, control and laboratory safety requirements for electrical equipment Part 1. General requirements (GB 4793.1- 2007, IEC 61010-1.2001, IDT)

GB 4793.4 measurement, control and laboratory use electrical safety laboratory equipment used in the treatment of medical materials to be autoclaved Particular Seek (GB 4793.4-2001, idt IEC 61010-2-041.1995)

GB/T 7307 55 ° non-sealing pipe thread (GB/T 7307-2001, eqv ISO 228-1.1994)

GB 9969.1 Instructions General Industrial Products

GB/T 12244 valve general requirements

GB/T 14710 Medical electrical equipment environmental requirements and test methods

GB/T 16839.2-1997 thermocouple Part 2. Tolerances (idt IEC 60584-2. 1982)

GB 18281.3 Sterilization of health care products - Biological indicators - Part 3. Biological

indicators for moist heat sterilization (GB 18281.3- 2000, idt ISO 11138-3.1995)

GB/T 19971 Sterilization of health care products Terminology (

GB/T 19971-2005, ISO /T S11139.2001, IDT)

3 Terms and Definitions

GB/T 19971 and identified the following terms and definitions apply to this standard.

3.1 Reaches sterilization temperature measurement from the reference point, to all parts of the load has reached the sterilizing temperature desired time.