

ICS 11.080.10

CCS C47



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 8599-2023

Technical requirements for large steam sterilizers

大型压力蒸汽灭菌器技术要求

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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 GB 8599-2008 "Technical Requirements for Large Steam Sterilizers Automatic Control Type". Compared with GB 8599-2008, except In addition to structural adjustments and editorial changes, the main technical changes are as follows:

- a) Changed the scope of the standard (see Chapter 1, Chapter 1 of the.2008 edition);
- b) Changes in terms and definitions (see Chapter 3, Chapter 3 of the.2008 edition);
- c) Basic parameters are deleted (see 4.2 of the.2008 version);
- d) Changed the requirements for double-door sterilizers (see 5.1.1.2, 5.4.2 of the.2008 edition);
- e) Changed the requirements for testing connectors (see 5.1.1.3, 5.4.3 of the.2008 version);
- f) Normal working conditions are deleted (see 5.1 of the.2008 version);
- g) Changed the requirements for structure and sterilization chamber size (see 5.2.1.1, 5.2.3 of the.2008 edition);

1 Scope

GB 8599-2023 is a mandatory national standard for large steam sterilizers - the autoclaves that sterilise surgical instruments and equipment in hospital central sterile services departments. Steam sterilisation works only if the steam actually reaches every surface, and the ways it fails are all invisible: air trapped in a lumen or a wrapped pack insulates the surface inside it, steam that is wet or superheated does not transfer heat as it should, and a load that reaches temperature at the drain sensor may not have reached it in the middle of a pack. The instrument comes out looking identical either way, and it goes into a patient. Since the equipment is also a pressure vessel operated in a hospital, mandatory status is appropriate on two counts. This document defines the terms and definitions for large pressure steam sterilizers, specifies their classification and requirements, and describes the test methods. It applies to sterilizers with chambers above the size threshold it sets. Its implementation date is 1 October 2026. Under ICS 11.080.10 and CCS C47, it is written for sterilizer manufacturers, hospital CSSD departments, and the medical device regulators and inspection bodies.

This document defines the terms and definitions of large pressure steam sterilizers (hereinafter referred to as "sterilizers"), stipulates classifications, requirements, and describes experiment method. This document is applicable to sterilization chambers with side openings that can load at least one sterilization unit or a volume of not less than 60L and a vacuum function. Bacteria. This sterilizer is mainly used for sterilizing medical and health care products and their accessories (excluding liquid items, flammable and explosive items, biological waste, human sterilization of body tissue).

Note. Sterilizers designed and produced according to this document also need to consider the impact of environmental factors in the product life cycle. See Appendix A for environmental impact factors.

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/T 3768 Acoustic sound pressure method determines the sound power level and sound energy level of noise sources using a simplified method of enveloping the measuring surface above the reflecting surface. Yifa

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

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

3 Terms and definitions

The following terms and definitions as defined in GB 18278.1-2015 and GB/T 19971-2015 apply to this document.

3.1 Absolute pressureabsolute pressure The pressure with absolute vacuum as the zero reference.

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