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

GB 42125.11-2025

**Safety requirements for electrical equipment for measurement, control
and laboratory use - Part 11: Particular requirements for sterilizers and
washer-disinfectors used to treat medical materials**

测量、控制和实验室用电气设备的安全要求 第11部分：用于处理医用材料的灭菌
器和清洗消毒器的特殊要求

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1. Structure and drafting rules for standardization documents" Drafting. This document is Part 11 of GB (T)42125 "Safety requirements for electrical equipment for measurement, control and laboratory use". GB (T)42125 The following parts have been published.

1. General requirements;
2. Particular requirements for laboratory equipment for material heating;
3. Particular requirements for refrigeration equipment;
4. Special requirements for climate and environmental tests and other temperature regulation equipment;
5. Particular requirements for laboratory centrifuges;
7. Safety requirements for hand-held and hand-operated probe assemblies for electrical

measurement and test;

10.Particular requirements for insulation resistance measurement and dielectric strength test equipment;

11.Particular requirements for sterilizers and washer-disinfectors for processing medical materials;

14.Particular requirements for automatic and semi-automatic equipment for laboratory use for analytical and other purposes;

17.Particular requirements for equipment used by children in educational institutions;

18.Particular requirements for control equipment;

19.Particular requirements for electric control valve actuators. This document replaces GB 4793.4-2019 "Safety requirements for electrical equipment for measurement, control and laboratory use Part 4. Compared with GB 4793.4-2019, in addition to structural adjustments and editorial changes, The main technical changes are as follows:

1 Scope and purpose

GB 42125.11-2025 carries the particular safety requirements for sterilizers and washer-disinfectors used to treat medical materials, within the Chinese adoption of the IEC 61010 series. These machines concentrate an unusual set of hazards in one cabinet: a pressure vessel operating with saturated steam, surfaces and loads hot enough to cause severe burns, chemical disinfectants and in some cases ethylene oxide or hydrogen peroxide, a door interlock that must make it impossible to open a pressurised or hot chamber, and a process whose failure sends unsterile instruments into an operating theatre. The standard modifies the general requirements clause by clause to deal with that: the tests, the marking and documentation, the protection against electric shock, the protection against mechanical hazards and against hazards from mechanical functions such as the door and the loading system, the resistance to mechanical stress, the prevention of the spread of fire, the temperature limits and heat resistance, the protection against hazards from fluids, from released gases and substances and from explosion, and the components, interlocks and protective systems. It is a GB standard without the recommended suffix: compliance is mandatory in China.

Except for the following contents, Chapter 1 of GB/T 42125.1-2024 applies.

1.1.1 Equipment to which this document applies replace. Replace the existing entry with the following entry. This document is applicable to medical materials intended for use in medical institutions, veterinary medicine, pharmaceutical and laboratory fields under the environmental conditions of 1.4. Safety requirements for electrical equipment that is sterilized, cleaned, and disinfected. For example.

- a) sterilizers and disinfectors using steam and/or hot water as sterilization media;
- b) Sterilizers and disinfectors using toxic gases, toxic aerosols or toxic steam as sterilization media;
- c) sterilizers and disinfectors using hot air or hot inert gas as sterilization medium;
- d) Washer-disinfector.

1.1.2 Equipment not included in the scope of this document Increase. Add the following note after item f).

Note. IEC 60601-1.2005

3.63 defines medical electrical equipment as follows (item comments are ignored).
Electrical equipment having an applied part that transmits or extracts energy to a patient or detects such energy transmitted or extracted, such electrical equipment.

- a) has no more than one connection to a designated electricity supply network; and
- b) its manufacturer intends it to be used. 1) diagnosis, treatment and monitoring of patients; or 2) Eliminate or alleviate disease, injury or disability. Increase. Add a second paragraph after the alphabetical items. This document also does not apply to the following types of equipment. aa) Equipment used in hazardous atmospheres [see IEC 60079 (all parts)], where a flammable sterilizing agent is used to produce such an atmosphere inside the equipment Except for equipment in the environment (see

13.2.101 and 13.2.102); bb) Laboratory equipment for heating materials for purposes other than sterilization or disinfection (see GB/T 42125.2); cc) Laundry appliances [see IEC 60335-2-4, IEC 60335-2-7, IEC 60335-2-11 and ISO 10472 (all parts)], unless It is designed for sterilization of medical materials; dd) Dishwashers (see IEC 60335-2-5 and IEC 60335-2-58).

1.2.1 Aspects included in the scope of this document replace. Replace item g with the following).

11 Part

1.Particular requirements for sterilizers and washer-disinfectors used to process medical materials. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed and coordinated by the State Food and Drug Administration. The previous versions of this document and the documents it replaces are as follows:

---First published in.2001 as GB 4793.4-2001;

---In the first revision in.2019, GB 4793.8-2008 "Safety requirements for electrical

equipment for measurement, control and laboratory use" was incorporated. Part 2-042. Special requirements for autoclaves and sterilizers for treating medical materials with toxic gases and for laboratory use Requirements" (the previous versions of GB 4793.8-2008 are. GB 4793.8-2008);

GB (T)42125 "Safety requirements for electrical equipment for measurement, control and laboratory use" is planned to consist of 20 parts.

1. General requirements. The purpose is to specify the general safety requirements of electrical equipment for measurement, control and laboratory use and their accessories Require.
2. Particular requirements for laboratory equipment for material heating. The purpose is to specify the special requirements for laboratory material heating equipment. Security requirements.
3. Particular requirements for refrigeration equipment. The purpose is to specify the special safety requirements for refrigeration equipment used in measurement, control and laboratories Require.
4. Special requirements for climate and environmental tests and other temperature regulation equipment. The purpose is to specify climate and environmental tests Special safety requirements for testing and other temperature regulating equipment.
5. Particular requirements for laboratory centrifuges. The purpose is to specify special safety requirements for laboratory centrifuges.
6. Particular requirements for test or measuring circuit equipment. The purpose is to specify the special safety requirements of test or measuring circuit equipment. Require.
7. Safety requirements for hand-held and hand-operated probe assemblies for electrical measurement and testing. The purpose is to specify the safety requirements for hand-held and hand-operated probe assemblies. Safety requirements for head assemblies and related accessories.
8. Particular requirements for hand-held and hand-operated current sensors for electrical measurement and testing. The purpose is to specify the requirements for hand-held and hand-operated current sensors. Special safety requirements for current sensors.
9. Particular requirements for hand-held multimeters and other instruments for household and professional use capable of measuring mains supply voltage. It is used to specify special safety requirements for hand-held multimeters and other instruments for household and professional use that can measure mains supply voltage.
10. Particular requirements for insulation resistance measurement and dielectric strength test equipment. The purpose is to specify the output voltage AC 50V Safety requirements for equipment used for insulation resistance measurement and dielectric strength testing at