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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 27955-2020

Replacing GB 27955-2011

Hygienic requirements for low-temperature hydrogen peroxide gas plasma sterilizer

过氧化氢气体等离子体低温灭菌器卫生要求

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1 Scope

GB 27955-2020 is the Chinese national standard on hygienic requirements for low-temperature hydrogen peroxide gas plasma sterilizer, in the field of health care technology. It carries no /T suffix, which in the Chinese system means compliance is mandatory: a product or a practice within its scope has to meet it to be lawfully made, sold or carried out in China. It was issued on 9 April 2020 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 November 2020. Classification: ICS 11.080, CCS C50. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This Standard specifies the technical requirements, application range, precautions for use, inspection rules, inspection methods, marking and packaging, transportation and storage for the low-temperature hydrogen peroxide gas plasma sterilizer. This Standard is applicable to low-temperature hydrogen peroxide gas plasma sterilizers for sterilizing medical devices, appliances and articles that are not resistant to humidity and high temperature.

2 Normative References

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this document.

GB/T 191 Packaging - Pictorial Marking for Handling of Goods

GB/T 1616 Hydrogen Peroxide for Industrial Use

GB/T 16886.5 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity

GB/T 16886.10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

GB/T 16886.11 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity

GB 19192-2003 Hygienic Requirement for Contact Lens Care Solution GBZ 159 Specifications of Air Sampling for Hazardous Substances Monitoring in the Workplace GBZ/T 300.48 Determination of Toxic Substances in Workplace Air - Part 48: Ozone and Hydrogen Peroxide

4.1.1.2 The sterilization program includes three stages: conditioning stage, sterilization stage and ventilation stage, which can be repeated and crossed.

4.1.2 Conditioning stage

4.1.2.1 The lower limit of the pressure of the sterilization chamber shall be no higher than the pressure specified by the manufacturer, and shall be no higher than 80Pa.

4.1.2.2 The temperature of the inner wall of the sterilization chamber shall be no less than 45°C at the end of the conditioning stage.

4.1.2.3 If plasma occurs, the maintenance time and input power shall comply with the manufacturer's provisions; the measured value of the maintenance time shall be no less than the minimum value specified by the manufacturer; and the measured error of the input power shall be within ±10%.

4.1.2.4 If there is purification, the concentration and dosage of hydrogen peroxide after purification shall comply with the manufacturer's provisions, and the error shall be within ±5%.

4.1.2.5 An alarm shall be issued when the sterilized items are too wet.

4.1.3 Sterilization stage

4.1.3.1 The temperature of the inner wall of the sterilization chamber shall be no greater than 60°C; the sterilization effect of the minimum temperature of the equipment shall be verified.

4.1.3.2 The maintenance time of the sterilization stage shall comply with the manufacturer's provisions; and the measured value of the maintenance time shall be no less than the minimum value specified by the manufacturer.

4.1.3.3 The sterilization pressure range should comply with the manufacturer's provisions.

4.1.3.4 The hydrogen peroxide concentration range during the sterilization stage shall comply with the manufacturer's provisions.

4.1.3.5 The concentration of hydrogen peroxide in the sterilization chamber should be monitored in real time.

4.1.4 Ventilation stage

4.1.4.1 The lower limit of the pressure of the sterilization chamber shall be no higher than the pressure specified by the manufacturer, and shall be no greater than 80Pa.

4.1.4.2 When plasma occurs, the maintenance time and input power shall comply with the manufacturer's provisions. The measured value of the maintenance time shall be

4.5 Evaluation and monitoring of sterilization effect Half cycle full load operation, aseptic growth.

4.6.1 Environmental exposure

4.6.1.1 The sterilizer shall be equipped with a hydrogen peroxide decomposition (filter) device and an alarm to prompt replacement function. The manufacturer shall specify its replacement cycle in the instruction manual.

4.6.1.2 In the workplace that meets the ambient ventilation conditions specified in the sterilizer instruction manual, the residual amount of hydrogen peroxide shall meet the 8h time-weighted allowable concentration (TWA) <= 1.5mg/m3.

4.6.2 Biocompatibility The items after sterilization shall be biocompatible with the human body.

4.6.3 Material compatibility Compatibility evaluation is carried out after sterilization of metal and non-metal material instruments. The result shall be basically no corrosion; and the evaluation result is limited to tested materials. The appearance of the sterilized material shall not have obvious changes, such as color, shape, and cracks, etc.

5 Application Range

5.1 The low-temperature hydrogen peroxide gas plasma sterilizer is suitable for medical equipment, appliances and articles that are not resistant to humidity or high temperature.

5.2 The sterilizer shall not be used to sterilize the following objects:

a) Items that are not completely dry;

b) Articles or materials that absorb liquids;

c) Items made of cellulose-containing materials or any other items containing wood pulp;

d) One-end occluded cavity;

e) Liquid or powder;

f) Single-use items; Run the sterilizer in accordance with the instruction manual provided by the manufacturer to determine whether it satisfies

4.1.1.1 and 4.1.1.2.

8.1.2 Inspection in conditioning stage

8.1.2.1 Connect the pressure measuring device to the pressure test port of the sterilization chamber; run the sterilization cycle to determine whether it satisfies 4.1.2.1.

8.1.2.2 Use the temperature sensor to measure the inner wall of the sterilization chamber; and run the sterilization cycle to determine whether it satisfies 4.1.2.2.

8.1.2.3 Use a stopwatch to measure the time of plasma in generation stage; a dedicated power meter to measure the operating power of the plasma generator; run the sterilization cycle to determine whether it satisfies 4.1.2.3.

8.1.2.4 Run the sterilization cycle. After the purification stage is over, stop the operation of the device; disassemble the purification device; extract the hydrogen peroxide solution; measure the concentration according to the method specified in Technical Standard for Disinfection (2002 Edition), and determine whether it satisfies 4.1.2.4.

8.1.3 Inspection in sterilization stage

8.1.3.1 Use the temperature sensor to measure the inner wall of the sterilization chamber; run the sterilization cycle to determine whether it satisfies 4.1.3.1.