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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 27949-2020

Replacing GB/T 27949-2011

General requirements of disinfectant of medical instruments

医疗器械消毒剂通用要求

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1 Scope

GB 27949-2020 is the Chinese national standard on general requirements of disinfectant of medical instruments, 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 raw material requirements, technical requirements, inspection methods, methods of use, identification, packaging, storage, transportation requirements for the chemical disinfectant for the disinfection and sterilization of medical instruments. This standard applies to disinfectants for medical items. This standard does not apply to sterilization equipment with sterilization factor generators and gas or disinfection and sterilization products that play a role after being vaporized under certain conditions.

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 standard.

GB/T 191 Packaging - Pictorial marking for handling of goods

GB 30689 Hygienic requirements for endoscope automatic cleaning and disinfecting machine GBZ 2 (All parts) Occupational exposure limits for harmful factors in the workplace

WS 507 Technical specification for cleaning and disinfection of soft endoscope Technical specification for disinfection (2002 edition) [Ministry of Health (WFJF [2002] No.282)] Technical specification for inspection of disinfection effect of endoscope cleaning and disinfecting machine (for trial) [Ministry of Health (WFJF [2003] No.330)] Pharmacopoeia of the people's Republic of China (2015 edition, four volume)

5.5.2 Requirements for simulated field test

5.5.2.1 Sterilizer At the minimum action concentration specified in the instruction manual and the dose of 50% of the shortest action time, if there is no growth of viable bacteria [Bacillus subtilis black variant (ATCC9372) spores] on the simulated medical item to be tested, it shall determine that the simulated field sterilization test of the medical item is qualified.

5.5.2.2 High-level disinfectant At the minimum action concentration specified in the instruction manual and the dose of the shortest action time, if the killing or logarithmic value of the spores of Bacillus subtilis black variant (ATCC9372) on the simulated medical item to be tested is not less than 3.00, it shall determine that the simulated field sterilization test of the medical item is qualified.

5.5.2.3 Intermediate-level disinfectant At the minimum action concentration specified in the instruction manual and the dose of the shortest action time, if the killing or logarithmic value of the Mycobacterium (ATCC19977) on the simulated medical item to be tested is not less than 3.00, it shall determine that the simulated field sterilization test of the medical item is qualified.

5.5.2.4 Low-level disinfectant Among the Staphylococcus aureus (ATCC6538), Pseudomonas aeruginosa (ATCC15422), Candida albicans (ATCC10231), select the microorganism with the strongest resistance to the tested disinfectant as the experimental microorganism. At the minimum action concentration specified in the instruction manual and the dose of the shortest action time, if the killing or extinction log- value of the microorganisms tested on the simulated medical item shall not be less than 3.00, it shall determine that the simulated field sterilization test of the medical item is qualified.

5.6 Requirements for disinfectants used in conjunction with disinfection instruments The special purpose disinfectants used in conjunction with the relevant disinfection and

sterilization devices, such as disinfectants for endoscopes, disinfectants for dialysis machine's pipelines, etc., shall meet the requirements of corresponding disinfection and sterilization devices such as WS507,

GB 30689 as well as relevant national standards. It shall verify the simulated disinfection and sterilization effects used in conjunction with related equipment. It is determined according to the relevant test methods in the "Technical specifications for disinfection" (2002 edition).

7.1 General

7.1.1 Medical items are preferred to be handled by thermal disinfection and sterilization.

7.1.2 The method of use shall comply with the standards and specifications of various types of disinfectants.

7.1.3 Before disinfecting or sterilizing the newly launched medical items, it shall first remove the oil stains and protective films; then use detergent to wash it to remove the grease; dry it.

7.1.4 Before disinfection or sterilization of contaminated medical items after use, they shall be fully cleaned and dried; the shaft joint shall be opened during treatment to fully expose it to disinfectant.

7.1.5 The sterilant which needs to be diluted before use as well as the high and intermediate level disinfectant shall be diluted by purified water, to avoid the influence of calcium, magnesium and other impurities on the disinfection effect.

7.2 Soak disinfection

7.2.1 Immerse the medical item to be treated in the disinfectant to make it completely submerged; then cover the disinfection container to let it action for the specified time.

7.2.2 For high-critical and intermediate-critical medical items, after the completion of disinfection and sterilization and before use, it shall use sterile water to rinse it clean or use other methods to remove residual disinfectant.

7.2.3 After immersed sterilization, the medical item shall avoid secondary contamination during the process of washing, transferring, storing. Among them, high-critical medical items shall be stored aseptically after sterilization; intermediate-critical medical items shall be clean-stored after sterilization or high-level disinfection; low-critical medical items shall be clean-stored after low and intermediate-level disinfection.