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

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**Hygienic standard of disinfection for single use medical
products**

(English Translation)

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1 Subject content and scope

This Standard specifies the single use medical products' hygiene standards, before and after sterilization and disinfection. This Standard provides the quality control of hygiene requirements to the manufacturing process such as manufacturing, assembly, packaging workshop, and manufacturing workers' hands in manufacturing enterprises of single use medical products (including sterilized and disinfected single use medical products).

This Standard applies to manufacturing enterprises of all types of single use medical products. And it also applies to sterilization and disinfection service organizations.

2 Normative references

GB 7918.2 Standard methods of microbiological examination for cosmetics -Standard plate count
 GB 8368 Medical infusion sets for single use
 GB 8369 Transfusion sets for single use
 GBJ 4883 Standards for sewage drainage in hospitals (Trial)
 Pharmacopoeia of the People's Republic of China (1990 Edition)

3 Terms

3.1

Sterilization. USE physical or chemical methods to kill all microorganisms on the media, so as to make them sterile.

3.2 Disinfection. USE physical or chemical methods to kill or clear all pathogenic microorganisms on the media, so as to make them harmless.

3.3 Sterilized single use medical products. The single use medical products that enter

into the body tissues; that are sterile, non-pyrogenic, non-hemolytic reactions, without abnormal toxicity; that have been inspected to be conformance; that must be sterilized before exiting out of the factory; and that can be used directly.

4 Sterilization and disinfection standards

4.1

Single use medical products must be sterilized and disinfected by ethylene oxide, ionizing radiation or other methods that have are determined qualified by Ministry of Health. All sterilization and disinfection equipment used must have a product license and hygiene license.

4.2

When single use medical products exit the factory after being sterilized or disinfected by ethylene oxide, the ethylene oxide residues shall be not more than 10µg/g.

4.3

Microbial indicators of sterilization and disinfection.

4.4

Evaluation criteria of sterilization and disinfection effects.

4.4.1

Evaluation criteria of sterilization effects.

4.4.1.1

Ethylene oxide sterilization. USE *Bacillus subtilis* var.niger (ATCC9372) as indicator bacteria, the inactivation index reaches 106.

4.4.2.4

Abnormal toxicity, pyrogen, and hemolytic reaction tests of products shall be conducted according to the specifications of GB 8368, 8369.

4.5

Requirements for sterilization and disinfection quality control.

4.5.1

It shall formulate the working systems, sterilization or disinfection procedures, and technical parameters according to business requirements of the organization.

Records of each-time operating conditions, inspection procedures, and results must be made, and be placed in files for future reference.

5.1 Hygiene requirements for plant

5.1.1

The plant shall be located at more than 500 meters away from main roads, docks, garages, and other serious air and water polluted areas. The surrounding environment shall be clean and green to prevent dust. Plants in manufacturing areas shall meet "Four Nos" - no water, no weeds, no garbage, and no mosquitoes breeding grounds.

5.2.1 Layout of workshops shall comply with the manufacturing process. Parts

manufacturing, assembly, packaging, transportation, etc. shall not be reversed and cross. Raw materials transported-in and products transported-out shall have strict regulations. Disinfected or sterilized items and non-disinfected or unsterilized items must be placed and transported separately.

5.2.5 Products produced shall be packaged timely. Means of transport shall be dedicated. Products packaged shall be stored at a non-corrosive-gas, well ventilated clean room with relative humidity less than 80%.

5.2.6 The concentration or amount of toxic and hazardous substances generated during the manufacturing shall comply with the relevant national standards.

5.3.1 Personnel engaging in production and disinfection and sterilization must have

an annual medical examination before being on the job. Patients with active tuberculosis, viral hepatitis, dysentery, typhoid fever or chronic carriers, gonorrhea and purulent or exudative dermatitis must not engage in this work.

6.1 Manufacturing enterprises must have the test equipment and measurement

instruments that guarantee product quality, and set up quality control room.

6.2 Requirements for self-test of manufacturing enterprises.

6.2.2 At the key operating points of workshop (control area), CONDUCT one-time total bacteria number detection for the air, objects' surfaces, and manufacturing workers' hands every week.

6.2.3 For each batch of products, SELECT randomly 10 pieces of samples to conduct initial contaminating bacteria number AND sterile detection of after-sterilization OR bacteria number detection after disinfected.

7.1 Each set of products shall be packaged and sealed in plastic bags. It shall have

the following marks on small packages.

7.2 Middle package shall be sealed by plastic bags, and shall have the following marks.

7.3 It shall have the following marks on large packing cases.

8 Test methods

REFER to Annex A~G.

Annex A

Detection method of the total number of bacteria in the air (Supplement) A1 DETERMINE the total number of bacteria in the air in dynamic state.

A2 USE plate exposure method. For the workshops larger than 30m², at five points of east, west, south, north, and center (1m away from the wall). For the workshops less than 30m², at three points of inside, middle, and outside of a diagonal line. Sampling height is at 1.5m. PLACE ordinary nutrient agar plates (diameter of 9cm) according to the above sampling points and height. CLOSE the lid immediately after exposing for 15min. OBSERVE the result after cultured at 37°C incubator for 24h. WORK OUT the average number of bacteria of 5 or 3 sampling points. The calculation formula is shown in Formula (A1).

Annex B

Detection method of the total amount of bacteria on object surfaces and manufacturing personnel's hands (Supplement) B1 Sampling method PUT the sterilization specification-plate with the inner diameter of 5cmx5cm ONTO the surface of objects to be tested. TAKE 1~4 parallel samples according to the surface area of objects. USE cotton