DOI: 10.11910/j.issn.2791-2043.2023.2.02

ICS 11.080
C 50

GB

National Standard of the People's Republic of China

GB 27955—2020
Substitute for GB 27955—2011

Hygienic Requirements for Low-temperature Hydrogen Peroxide Gas Plasma Sterilizer

Issued on April 09, 2020 Implemented on November 01, 2020

Issued by:

State Administration for Market Regulation
Standardization Administration of the People's Republic of China

PREFACE

All technical provisions in this document are mandatory.

This document is drafted following the rules given in GB/T 1.1-2009.

This document substitutes for *General requirements for low-temperature hydrogen peroxide gas plasma sterilizer* (GB 27955-2011). Compared with GB 27955-2011, the main technical changes in this document are as follows:

- The applicability of the requirements is modified (see Chapter 1 and Chapter 1 in the 2011 edition);
- The normative references are modified (see Chapter 2 and Chapter 2 in the 2011 edition);
- Terms and definitions are modified (see Chapter 3 and Chapter 3 in the 2011 edition);
- Naming is deleted (see Chapter 4 in the 2011 edition);
- Sterilization procedures, hydrogen peroxide sterilants, display devices, recording and output devices are added (see 4.1, 4.2, 4.3, and 4.4);
- Evaluation and monitoring of sterilization effect are modified (see 4.5 and 5.1.2 in the 2011 version);
- Safety requirements are modified (see 4.6 and 5.2 in the 2011 version);
- Test scope is modified (see 5.1);
- The test methods for safety are modified (see 4.6 and 5.2 in the 2011 version);
- Precautions for use are modified (see Chapter 6 and Chapter 8 in the 2011 edition);
- Biomonitoring methods for low-temperature hydrogen peroxide gas plasma sterilization are added (see Appendix B).

This document is issued and centrally administered by the National Health Commission of the People's Republic of China.

Drafting units: National Institute of Environmental Health, Chinese CDC, Peking Union Medical College Hospital, Peking University Hospital of Stomatology, Comprehensive Supervision and Law Enforcement Service Center of Health Commission of Hebei Province, Law Enforcement and Supervision Bureau of Health Commission of Shandong Province, Renmin Hospital of Wuhan University, the Affiliated Hospital of Qingdao University, Shandong Provincial Hospital Affiliated to Shandong First Medical University, Health Supervision Institute of Jiangxi Province, Zhejiang Provincial Center for Disease Control and Prevention, Sir Run Run Shaw Hospital affiliated with Zhejiang University School of Medicine.

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Previous versions of this document include:

— GB 27955-2011.

Hygienic Requirements for Low-temperature Hydrogen Peroxide Gas Plasma Sterilizer

1. Scope

This document specifies the technical requirements, the scope of application, precautions for use, inspection rules, test methods, marking and packaging, transportation, and storage of the low-temperature hydrogen peroxide gas plasma sterilizer.

This document applies to the low-temperature hydrogen peroxide gas plasma sterilizer for sterilizing medical devices, instruments and articles that are not resistant to moisture or high temperature.

2. Normative References

The following documents are essential for applying this document. If the reference document is dated, only the dated version is applicable to this document; if not, its latest version (including all modification items) is 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 medi-

cal 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 (2002) (Announced by Ministry of Health of PRC [2002] No. 282)

3. Terms and Definitions

The following terms and definitions apply to this document.

3.1 Plasma

A mixture of ions, electrons, and neutral molecules or atoms.

Note: The plasma in this document is formed by the ionization of gas molecules in the electric field.

3.2 Low-temperature hydrogen peroxide gas plasma sterilizer

A device for sterilizing with hydrogen peroxide gas at 60° C and decomposing residual hydrogen peroxide with plasma.

3.3 Conditioning stage

The process of vacuuming and heating the hydrogen peroxide before injection into the capsule in preparation for sterilization, including hydrogen peroxide purification and plasmaization.

3.4 Sterilization stage

The process of sterilization utilizing hydrogen peroxide gas under a certain concentration, temperature and pressure for a certain period after the hydrogen peroxide into the capsule.

3.5 Ventilation stage

The process of exhausting and decomposing hydrogen peroxide gas, including vacuum exhaust and plasmaization.

4. Technical Requirements

4.1 Sterilization procedures

4.1.1 Overview

4.1.1.1 Sterilization procedures should be set up for sterilizers according to the sterilized object, including at least the procedures for the surface, lumen and flexible endoscope of medical devices.

4.1.1.2 The sterilization process consists of three phases: the conditioning stage, the sterilization stage and the ventilation stage. They can be adopted repeatedly and alternately.

4.1.2 Conditioning stage

4.1.2.1 The lower pressure limit of the sterilizer capsule shall be no higher than the pressure specified by the manufacturer and shall be no greater than 80 Pa.

4.1.2.2 The temperature of the inner wall of the sterilizer capsule should be not less than 45° C at the end of the conditioning stage.

4.1.2.3 If the plasma is observed, the maintenance period and input power should comply with the manufacturer's specifications. The value of the maintenance period measured shall be not less than the minimum value specified by the manufacturer. The measured error of input power shall be within ± 10%.

4.1.2.4 If purification is observed, the purified hydrogen peroxide concentration and dose should be within ± 5% of the manufacturer's specification.

4.1.2.5 Give an alarm if sterilized items get wet.

4.1.3 Sterilization stage

4.1.3.1 The temperature of the inner wall of the sterilizer capsule shall be not more than 60° C. The sterilization effect at the minimum temperature set by the device shall be verified.

4.1.3.2 The maintenance period shall comply with the manufacturer's specifications and the value of the maintenance period measured shall be no less than the minimum value specified by the manufacturer.

4.1.3.3 The sterilization pressure range shall comply with the manufacturer's specifications.

4.1.3.4 The range of hydrogen peroxide concentration in the sterilization stage shall comply with the

manufacturer's specifications.

4.1.3.5 Real-time monitoring of hydrogen peroxide concentration in the sterilizer capsule is recommended.

4.1.4 Ventilation stage

4.1.4.1 The lower pressure limit of the sterilizer capsule should be no higher than the pressure specified by the manufacturer and should be no greater than 80 Pa.

4.1.4.2 If plasma is observed, the maintenance time and input power should follow the manufacturer's specifications. The value of the maintenance time measured shall be no less than the minimum value specified by the manufacturer. The measured error of input power shall be within ±10%.

4.1.4.3 The residual value of hydrogen peroxide in the sterilizer should not exceed 30 mg/kg•H_2O at the end of the ventilation stage.

4.2 Hydrogen peroxide sterilant

4.2.1 The hydrogen peroxide sterilant should meet the quality requirements of 60% hydrogen peroxide according to GB/T 1616. The concentration of hydrogen peroxide during the validity period is 53% to 60%.

4.2.2 The sterilizer should be equipped with the hydrogen peroxide provided by the manufacturer. The validity period in use is not less than 10 days and the concentration is 53% to 60%.

4.3 Display devices

4.3.1 The sterilizer shall have the following indicators

a) Temperatures of the sterilizer bulkhead and door.

b) Pressure of the sterilizer capsule.

c) Input power of plasma.

d) Name and running time of the sterilization procedure in each stage.

e) Operation alarms and codes.

4.3.2 The hydrogen peroxide concentration is recommended to display in the sterilizer capsule during the sterilization stage.

4.4 Recording and output devices

4.4.1 The sterilizer shall record and export following indicators in real-time

a) Temperatures of the sterilizer bulkhead and door.

b) Pressure of the sterilizer capsule.

c) Input power of plasma.

d) Name and running time of the sterilization procedure in each stage.

e) Alarm codes.

4.4.2 The sterilizer is recommended to record and export the hydrogen peroxide concentration in the sterilizer capsule in real-time.

4.5 Sterilization effect evaluation and monitoring

Half-cycle full-load operation with no bacterial growth.

4.6 Safety

4.6.1 Environmental exposures

4.6.1.1 The sterilizer should be equipped with a hydrogen peroxide decomposer (filter) with an alarm prompting the replacement, and the instruction manual provided by the manufacturer should specify the replacement cycle.

4.6.1.2 In a workplace that meets the ventilation conditions according to the instruction manual, the residual hydrogen peroxide should be ⩽ 1.5mg/m^3 of 8-hour time weighted average (TWA).

4.6.2 Biocompatibility

The sterilized articles should be biocompatible with the human body.

4.6.3 Material compatibility

Evaluate the compatibility after sterilization of metallic and non-metallic material devices. The result should be hardly non-corrosive. The evaluation is limited to the tested materials. There should be no visible changes in the appearance of the sterilized material, such as color, shape and cracks.

5. Application scope

5.1 The low-temperature hydrogen peroxide gas plasma sterilizer applies to medical devices, appliances and articles that are not resistant to moisture or high temperature.

5.2 The sterilizer shall not apply to the following objects

a) Articles that are not completely dry;

b) Articles or materials that absorb liquids;

c) Articles made of cellulose materials or any other articles containing woody pulp;

d) The inner lumen that is occluded at one end;

e) Liquids or powders;

f) Disposable articles;

g) Implants;

h) Devices that cannot be vacuumed;

i) Devices labeled for only adopting autoclave sterilization;

j) Devices with internal parts that are difficult to clean.

6. Precautions for use

6.1 Before loading into the sterilizer, sterilized articles should be effectively and correctly cleaned and dried.

6.2 The packaging materials should be special bags or medical non-woven fabrics.

6.3 The sterilized articles should be loaded strictly according to the sterilizer instructions to prevent poor sterilization effect due to incorrect loading.

6.4 High-concentration hydrogen peroxide may burn the skin. So, personal protective measures shall be taken and the sterilizer shall be properly operated.

6.5 The concentration and dose of the hydrogen peroxide used as sterilant shall be consistent with the requirements specified in the sterilizer manual.

6.6 The device shall be maintained strictly following the sterilizer manual.

7. Test rules

7.1 Type inspection

Type test includes 4.1.2, 4.1.3, 4.1.4, 4.2, 4.5 and 4.6.

7.2 Factory inspection

Factory test includes 4.1, 4.2, 4.3, 4.4 and 4.5.

8. Test methods

8.1 Test of sterilization procedure

8.1.1 General requirementsOperate the sterilizer according to the instruction manual provided by the manufacturer to determine if it complies with 4.1.1.1 and 4.1.1.2.

8.1.2 Test in the conditioning stage

8.1.2.1 Connect the pressure measuring device to the pressure test port of the sterilizer capsule, conduct the periodic sterilization, and determine if it complies with 4.1.2.1.

8.1.2.2 Measure the interior wall of the sterilizer capsule using a temperature sensor, conduct the periodic sterilization, and determine if it complies with 4.1.2.2.

8.1.2.3 Calculate the plasma emergence phase of time using a stopwatch and calculate the operating power of the plasma generator using a specialized wattmeter to determine if it complies with 4.1.2.3.

8.1.2.4 Conduct the periodic sterilization. After the purification phase, stop operation and disassemble the purification device. Extract the hydrogen peroxide solution and measure the concentration according to the method given in *Technical Standard for Disinfection* (2002 version) to determine whether it complies with 4.1.2.4.

8.1.3 Test in the sterilization stage

8.1.3.1 Measure the interior wall of the sterilizer capsule using a temperature sensor. Conduct the periodic sterilization and determine if it complies with 4.1.3.1.

8.1.3.2 Conduct the periodic sterilization, and calculate the sterilization period using a stopwatch to determine if it meets 4.1.3.2.

8.1.3.3 Connect the pressure measuring device to the pressure test port of the sterilizer capsule, conduct the periodic sterilization, and determine if it complies with 4.1.3.3.

8.1.3.4 The hydrogen peroxide concentration sensor should be calibrated periodically to determine if it complies with 4.1.3.4.

8.1.4 Test in the ventilation stage

8.1.4.1 Connect the pressure measuring device to the pressure test port of the sterilizer capsule, conduct the periodic sterilization and determine if it complies with 4.1.4.1.

8.1.4.2 Conduct the periodic sterilization. Calculate the plasma emergence phase of time using a stopwatch and calculate the operating power of the plasma generator using a specialized wattmeter to determine if it complies with 4.1.4.2.

8.1.4.3 Conduct the periodic sterilization. Then

take the test equipment processed by one periodic sterilization (2 m polytetrafluoroethylene (PTEF) lumen with 1 mm inner diameter and 500 mm stainless steel lumen with 1 mm inner diameter), soak them in 100 mL of purified water for 1 minute respectively to make the samples to be tested. Following the method provided in 5.1.5 in GB 19192-2003, each sample shall be measured twice, and the average value is taken to determine whether it complied with 4.1.4.3.

8.2 Test of hydrogen peroxide

Determine whether the peroxide sterilant and the information provided by the manufacturer comply with 4.2.1 and 4.2.2.

8.3 Test of display device

Operate the sterilizer and determine if it complies with 4.3.

8.4 Test of recording and output devices

Operate the sterilizer and determine if it complies with 4.4.

8.5 Test of sterilization effect and monitoring

Test following Appendix A or Appendix B and determine whether to comply with 4.5.

8.6 Safety test

8.6.1 Environmental exposure to hydrogen peroxide

8.6.1.1 Check the sterilizer and the instruction manual to determine if it complies with 4.6.1.1.

8.6.1.2 When conducting in the operating environment specified in the manufacturer's instructions, test the materials following the methods given by GBZ/T 300.48. Calculate the test results according to the requirements in GBZ 159 to determine if they comply with 4.6.1.2.

8.6.2 Test of biocompatibility

Prepare samples according to Appendix C. Test metal and non-metal sterilized articles within 4 hours after low-temperature hydrogen peroxide gas plasma sterilization. Conduct a cytotoxicity test according to GB/T 16886.5 and the result should be negative. If the result is positive, perform the subcutaneous injection response test according to the stimulated and delayed hypersensitivity test method provided in GB/T 16886.10, and the subcutaneous intravenous injection response test according to the systemic toxicity test method provided in GB/T 16886.11. If both results are negative, it is biocompatible with the human body.

8.6.3 Test of material compatibility

Prepare samples of metallic and non-metallic materials according to Appendix D. Samples are evaluated for metallic corrosion following Part 2.2.4 of the *Technical Standard for Disinfection* (2002 version); the corrosion of non-metallic materials is evaluated by the manufacturer. Determine if they comply with 4.6.3.

9. Marking and packaging

9.1 Marking

The logo and label used shall conform to the requirements of GB/T 191 C Packaging

The markings shall conform to the general requirement for the label and instruction book of disinfection products.

10. Transportation and storage

10.1 Transportation

The materials shall be transported by general vehicles or according to the contract requirements, with measures to prevent rain, moisture, shock and severe vibration.

10.2 Storage

After packing, store the materials in a room with a temperature ⩾ 0℃, relative humidity ⩽ 93%, no corrosive objects, and adequate ventilation.

Appendix A

(Normative Appendix)

Test Methods of Sterilization Effect

A. 1 Methods and principles

The test adopts the common rigid stainless-steel pipe and soft PTFE pipe as the simulated lumen to verify the microbiological sterilization effect. The test should adopt a capped-open seamless pipe for testing. The gas tightness should be ensured if there is a seam. Put a carrier infected with bacterial spores in the center of the pipe and per-

form sterile culture through a half-cycle sterilization cycle. Evaluate the microbiological sterilization effect by referring to Bacillus stearothermophilus as the indicator bacteria. If the culture results of all tests are negative, the results are determined to be qualified.

A. 2 Biologic indicator

Bacillus stearothermophilus (ATCC7953).

A. 3 Testing devices

A.3.1 Carrier: Apply the bacillus suspension evenly on the stainless-steel test sample with a diameter of 0.4 mm and length of 20 mm to 30 mm, to the extent that the pipe is not blocked after staining. The positive bacterial count recovered of Bacillus stearothermophilus should reach 1×10^6 CFU/carrier to 5×10^6 CFU/carrier. Dry naturally at room temperature before use.

A.3.2 Lumen testing: The test should adopt a capped-open seamless pipe for testing. The gas tightness should be ensured if there is a seam.

A.3.3 Seamless stainless-steel pipe, 10 pcs.

A.3.4 Seamless PTFE pipe, 10 pcs.

A.3.5 TSB medium of Bacillus stearothermophilus: 17.0g of dry-powder tryptone, 3.0g of phytone, 5.0g of sodium chloride, 2.5g of dipotassium hydrogen phosphate, 2.5g of glucose, a total of 30g dissolved in 1L of distilled water to make tryptone soy broth (TSB) medium.

A. 4 Operation procedure

A.4.1 Deliver the stained carrier to the center of the stainless-steel pipe to make 10 test samples. Place the 10 samples in the device cassette evenly and in parallel. Wrap them in a double layer of non-woven fabric and place them in the sterilizer capsule. If the capsule has only one compartment, the 10 samples are placed parallel in the center of the capsule (see Figure A. 1). If the capsule has two compartments, the 10 samples are placed evenly in the center of the top and bottom compartments of the capsule (see Figure A.2).

Conduct half-cycle sterilization according to

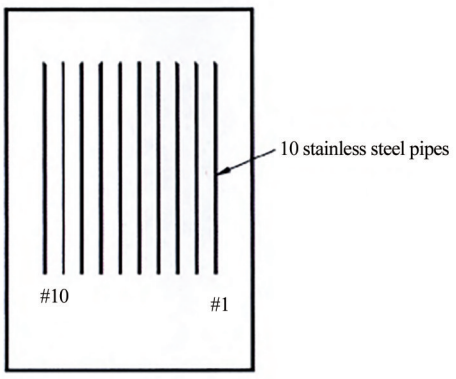

Figure A.1

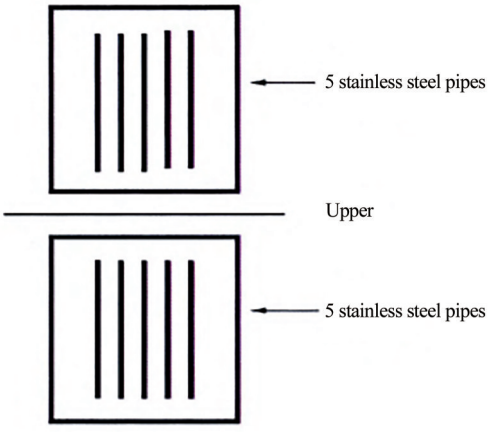

Figure A.2

the sterilization procedure in *Technical Standard for Disinfection* (2002 version). After sterilization, remove the bacterial spore carriers to a TSB medium aseptically and culture them at 56° C for 48 hours. If no bacterial growth was observed, the culture should be continued until Day 7. If no bacterial growth is observed again, the results are determined to be negative.

A. 4.2 Deliver the stained carrier to the center of the PTEF pipe using a fine wire to make 10 test samples. Place the 10 samples in the device cassette evenly and in parallel. Wrap them in a double layer of non-woven fabric and place them in the sterilizer capsule. If the capsule has only one compartment, the 10 samples are placed parallel in the center of the capsule (see Figure A. 3). If the capsule has two compartments, the 10 samples are placed evenly in the center of the top and bottom compartments of the capsule (see Figure A.4).

Conduct half-cycle sterilization according to

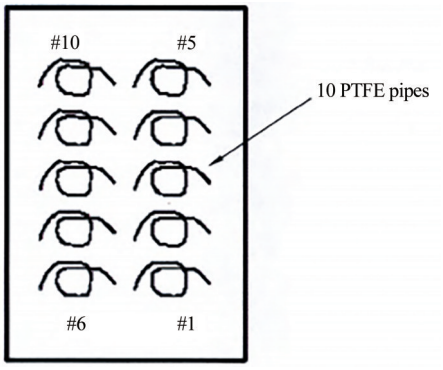

Figure A.3

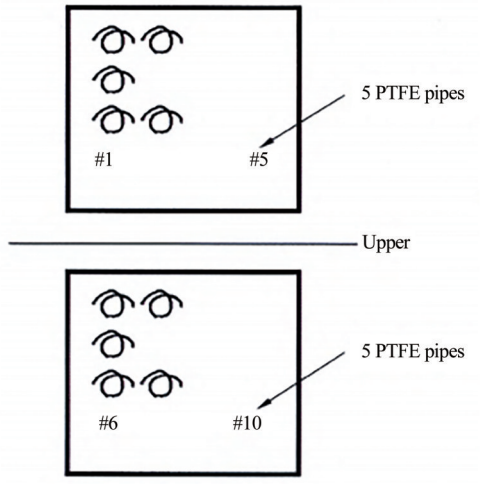

Figure A.4

the sterilization procedure in *Technical Standard for Disinfection* (2002 version). After sterilization, remove the bacterial spore carriers to a TSB medium and culture them at 56° C for 48 hours. If no bacterial growth was observed, the culture should be continued until Day 7. If no bacterial growth is observed again, the results are determined to be negative.

A. 5 Result calculation

The simulating test shall be repeated for Bacillus stearothermophilus for both materials above. The microbiological tests shall be repeated five times for each.

A. 6 Result determination

If no bacterial growth is observed, the culture results are determined to be negative and the results are determined to be sterilization qualified.

Appendix B

(Normative Appendix)
Biomonitoring method for low-temperature hydrogen peroxide gas plasma sterilization

B. 1 Bacillus stearothermophilus bioindicator(s)

The carriers should have no adsorption of hydrogen peroxide. The number of bacteria on each carrier should be 1×10^6 CFU. The resistance of the bacterium used to hydrogen peroxide gas should be stable and qualified. The products used should meet the relevant national regulatory requirements for the sterilization quality of the sterilizer by the lumen bio-monitoring package or non-lumen biomonitoring package and be biologically monitored.

B. 2 Monitoring methods for lumen biomonitoring kits

Sterilization of lumen instruments should be monitored using a lumen bio Process Challenge Device (PCD) or a validation device equivalent to the lumen bio PCD. The device should be proven to be a sterilization challenge device with equal or even greater resistance to the lumen PCD. The lumen biomonitoring kit should be placed in the most difficult-to-sterilize part of the sterilizer (keep away from the hydrogen peroxide injection port, e. g., behind the lower device shelf of the sterilizer capsule, according to the manufacturer's instructions) for sterilization at full load. Immediately after the sterilization cycle, remove the lumen bio PCD from the sterilizer, culture it at 56°C ± 2°C for seven days (or as per product instructions), and observe the culture results.

B. 3 Monitoring methods for non-lumen biomonitoring kits

When sterilizing non-lumen instruments, the non-lumen biomonitoring kit should be utilized for monitoring. Place the self-contained biological indicator in a Tyvek package and seal it. Then place the package in the most difficult-to-sterilize area of the

sterilizer (keep away from the hydrogen peroxide injection port, e.g., behind the lower device shelf of the sterilizer capsule, according to the manufacturer's instructions). Immediately after the sterilization cycle, remove the non-lumen biomonitoring package from the sterilizer, culture it according to the instruction of the self-contained biological indicator, and observe the culture results.

B. 4 Result determination

The culture result of the positive control group should be positive, and the negative group should be negative. If the culture result of the experimental group is negative, it is determined to be sterilization qualified. If the result is positive, it is determined to be sterilization failure, and the positive bacteria should be further identified whether they are indicator bacteria or caused by contamination.

Appendix C

(Normative Appendix)
Preparation of test samples

C.1 Take the metal and non-metal materials listed in the manual as the test samples. Each material shall be made into three samples of size 60 cm^2 (100 mm× 60 mm). The material should be medical grade.

C.2 Rinse each sample using a neutral instrument washing solution, and then rinse thoroughly with steaming water to remove surface contaminants and residual cleaning agents.

C.3 Wipe dry each sample using a non-woven cotton cloth. Blow dry using clean filtered air (or equivalent) to remove any remaining fibers from the sample.

C.4 Keep the dry and clean samples in a clean laboratory environment and prevent them from chemicals and hydrogen peroxide vapor.

C.5 Wrap samples of each material separately in a single layer of Tyvek bags to prevent the bacteria while allowing the hydrogen peroxide to penetrate.

C.6 Place the test sample flat in the sterilizer cartridge without the cap and place the cartridge in the center of the upper layer of the sterilizer capsule.

C.7 Set the sterilizer capsule temperature to the minimum and inject the maximum dose of hydrogen peroxide sterilant according to the manufacturer's instructions.

C.8 Perform full cycle sterilization.

Appendix D

(Normative Appendix)
Test of material compatibility

D. 1 Methods and principles

Determine no corrosion on the surface of the devices after several low-temperature hydrogen peroxide gas plasma sterilizations. The material compatibility of the sterilized device is measured to determine the compatibility of devices with hydrogen peroxide during sterilization.

D. 2 Sample preparation and operation procedures

D.2.1 Prepare the samples according to Part 3.4.2 in Technical Standard for Disinfection (2002 version).

Sample metal sheet: round, 24.00 mm diameter, 1.00 mm thick, pierced with a 2.00 mm diameter hole, and total surface area of about 9.80 cm2 (including the upper, lower and peripheral surfaces as well as the side of the hole). The finish is 6. The raw materials are as follows:

Carbon steel (specifications refer to GB/T 700)

Copper (specifications refer to GB/T 2059)

Aluminum (specifications refer to GB/T 1173)

Stainless steel (specifications refer to GB/T 1220)

Rinse each sample with a neutral instrument washing solution, then rinse thoroughly with evaporated water to remove surface contaminants and residual detergent. Wipe dry each sample using a non-woven cotton cloth. Blow dry using clean filtered air (or equivalent) to remove any residual fibers from the sample. Weigh each sample 3 times after the balance has returned to zero and with an accuracy of 0.1 mg. Take the average as the pre-test

weight (wear clean gloves and do not touch the sample by hand when weighing). Wrap the samples of each material separately in single-layer Tyvek bags to prevent the bacteria while allowing the hydrogen peroxide to penetrate.

D.2.2 Place the test sample flat into the sterilizer capsule without placing the cap. Place the cassette in the center of the top layer of the sterilizer capsule. Set the sterilizer capsule at the minimum temperature according to the manufacturer's instructions and inject the maximum dose of hydrogen peroxide. Then conduct the full cycle sterilization.

D.2.3 The number of cycles to verify that the sterilized device is not corroded shall be not less than 100 times.

D. 3 Testing

After sterilization, extract the samples and evaluate them for metal corrosion according to *Technical Standard for Disinfection* (2002 version).

D. 4 Result evaluation

Evaluate the results referring to 3.4.3 (9) in *Technical Standard for Disinfection* (2002 version). Observe the color change of the metal. If the corrosion rate of the metal surface is $R<0.01$, evaluate it as hardly non-corrosive. The evaluation of non-metallic surfaces shall follow the manufacturer's specifications.