AbleMed	**Plasma Sterilization Test Surface Effect Experiment Report**	Trial date: February 26, 2024
Produced by:Cai Botao	Acknowledgement: Musk.lyu	KANOU-QC-QR-064，Rev: A0

1. Scope of application:

The quality specifications and requirements described in this document apply to the anodized products provided by AbleMed®.

2. Purpose:

To test the performance of anodized surface treatment and whether it meets the requirements for medical use after the plasma sterilization process.

3. Definition:

Plasma: a mixture of ions, electrons and neutral molecules or atoms;

Hydrogen peroxide gas plasma low-temperature sterilizer: a device that sterilizes with hydrogen peroxide gas at 60°C and decomposes residual hydrogen peroxide with plasma;

Preparation period: the process of vacuum and heating before hydrogen peroxide is injected into the cabin to prepare for sterilization, and there may be a hydrogen peroxide purification plasma process;

Sterilization period: the process of hydrogen peroxide injection into the cabin to sterilize by relying on hydrogen peroxide gas under a certain degree of pressure for a certain period of time;

Analysis period: the process of discharging and decomposing hydrogen peroxide gas, including vacuum exhaust and plasma process;

Fading: the color of the product surface loses its brightness due to physical/chemical factors; becomes dull.

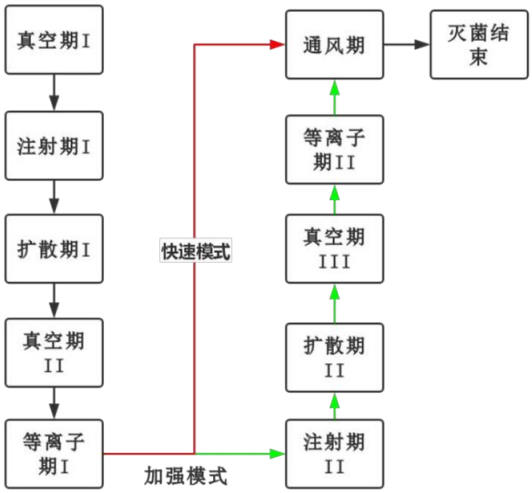
4. Reference standards:

GB 27955-2020 Hygienic requirements for hydrogen peroxide gas plasma low-temperature sterilizers

GB/T 1616 Industrial hydrogen peroxide

5. Test equipment name:

Model SQ-DZ 130 Hydrogen peroxide low-temperature plasma sterilizer.



Test requirements:

1). Hydrogen peroxide concentration: 58%~60%

2). Capsule specifications: single capsule capacity ≥3ml, single cartridge totaling 12 capsules.

3). Working temperature: 45℃~60℃

4). Sterilization time: rapid sterilization ≤30min; enhanced sterilization ≤50min; lumen sterilization ≤60min

5). Power requirement: 4.8KVA

6). Ambient temperature: 10~40℃

7). Relative humidity: not more than 80%

8). Vacuum pump: Use a rotary vane vacuum pump with extremely high vacuum and resistance to H2O2 corrosion, the ultimate vacuum can reach

0.04Pa

9) . Air filter: filtration accuracy ≤0.22μm

6.Test object: AbleMed products that need to be verified after various anodized surface treatment

7. Sterilization procedure

7.1 Overview

7.1.1 The sterilizer should have at least sterilization procedures for medical devices and flexible endoscopes according to the corresponding settings.

7.1.2 The sterilization procedure includes three stages: preparation period, sterilization period and analysis period, which can be repeated and crossed

7.2 Preparation period

7.2.1 The lower limit of the sterilization chamber pressure should not be higher than the pressure specified by the manufacturer and should not be greater than 8Pa

7.2.2 The inner wall temperature of the sterilization chamber should not be less than 45C at the end of the preparation period.

7.2.3 The power input during the plasma maintenance period should meet the requirements of the system. The actual value during maintenance should not be less than the minimum value specified by the manufacturer, and the actual measurement error of the input power should be within ±10%.

7.2.4 If purified, the concentration and dosage of hydrogen peroxide after purification shall comply with the manufacturer's regulations and the error shall be within 5%

7.2.5 An alarm shall be sounded when the sterilized items are too wet

7.3 Sterilization period

7.3.1 The temperature in the sterilization chamber shall not be greater than 60C; the sterilization effect of the equipment set at the lowest temperature shall be verified

7.3.2 The maintenance time of the sterilization period shall comply with the manufacturer's regulations and the actual measured value of the maintenance time shall not be less than the minimum value specified by the manufacturer.

7.3.3 The sterilization pressure range shall comply with the manufacturer's regulations.

7.3.4 The concentration range of hydrogen peroxide during the sterilization period shall comply with the manufacturer's regulations

7.3.5 Real-time monitoring of the peroxide gas concentration in the sterilization chamber shall be carried out.

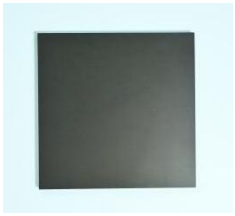
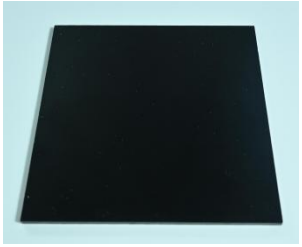
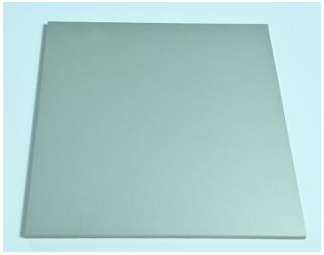
7.4 Analysis period

7.4.1 The lower limit of the sterilization chamber pressure shall not be higher than the pressure specified by the manufacturer and shall not be greater than 80Pa.

7.4.2 The plasma maintenance time and input power shall comply with the manufacturer's regulations, the actual measured value of the maintenance time shall not be less than the minimum value specified by the manufacturer, and the actual measured error of the input power shall be within ±10%.

7.4.3 After the desorption period, the residual peroxide value of the sterilized load should not exceed 30 mg/kg·H0

8.The test results are as follows:

Product No.	Color (with photos)		Result judgment criteria: No color difference before and after sterilization
	Before sterilization	After sterilization	
1	Bronze	 Bronze	Qualified
2	 Bright Black	Bright Black	Qualified
3	 silver	silver	Qualified