



Certificate number:
2025042503S



Test
CNASL
2954

Suzhou University
Testing Report from the Testing Center of th
e Ins-titute of Health and Environmental
Tehnology

Test Report

Report Number: SDWH-2025-32624

Sample Name: Disposable sterile medical device packaging bag

Test Items: Packaging verification test

Applicant Name: Anhui Mr Kang Packaging Co., LTD.

Suzhou University Institute of Health and Environmental Technology Testing Center

Address: No.199Ren'aiRoad,SuzhouIndustrialPark,China

Phone:0512-65880038

Fax:0512-65880038

Zipcode: 215123

Page1 of 8

Detection Report Description

I. Those who have objections to the test report results shall submit them to our center within 15 days from the date of receiving the report. No objections will be accepted after this period.

II. An inspection report without the official seal of the inspection unit is invalid.

III. An inspection report without the signatures of the preparer, reviewer, and approver is invalid.

IV. Any alterations to the inspection report are invalid.

V. The sample testing results are solely responsible for the submitted samples.

VI. The copy right of the inspection report belongs to the Inspection Center. If a copy is needed, it must be approved by the Center, and only the entire content can be copied.



Catalogue

	page number
Signature.....	4
Vacuum leakage test.....	5
Seal peeling test.....	6
Accelerated aging test.....	7



Test Report from the Testing Center of the Institute of Health and
Environmental Technology, Soochow University

Sample Name	Single-use sterile medical device packaging bag
Sample Submission Unit	Anhui Meirunkang Packaging Co., Ltd.
Sample collection date	6 January 2025
Specifications	Not provided
Lot number	Not provided
Surveillance project	Vacuum leakage test
	Seal peeling test
	Accelerated aging test

Editor : 田昕
proof reader : 李敏
Approver : 张明

苏州大学卫生与环境技术研究检测中心
日期: 2025年 01月 18日



Vacuum Leakage Test

Test Basis: Refer to ISO11607-2006, ASTM F 1980-07, ASTM D 3078-02 Method

Testing equipment: Vacuum pump (SDWH-097), Vacuum gauge (SDWH-329)

Condition of experiment :

Accelerate daging (60°C), high relative humidity (RH70-80%), low relative humidity (RH<20%), and low temperature (-20°C), Q₁₀=2

The equivalent duration of two years = 58 days
Number of samples = 10
Low relative humidity (<20 RH%) – 26 days
High relative humidity (70%-80% RH) – 28 days
Low temperature (<-20°C) – 4 days
est solution (distilled water) and evacuate

Test method : _____

Immerse the sealed package in the test solution (distilled water), under vacuum (-40 kPa). Due to the pressure difference, the test solution will enter the package through any leakage points.

Results: Ten samples were collected and tested respectively, with the following:

Sample Number	Leakage Condition
1	1
2	1
3	1
4	1
5	1
6	1
7	1
8	1
9	1
10	1

Conclusion: The packaging was tested and showed no leakage.

Date of trial completion: April 18,2025

Detector:Liu Chun li, Liang Yu

Seal Peeling Test

Test basis: Refer to ASTM F 88-07 and ASTM F 1980-07 methods.
Test environment temperature and humidity: Temperature 26°C, humidity 50%.
Test equipment: SZL-200 Digital Display Specialized Tensileand CompressiveTesting
Machine (SDWH-035)
Condition of experiment:
Accelerated aging (60°C), high relative humidity (RH70–80%), low relative humidity (RH 20 %), and low temperature (<-20°C), Q10=2

The equivalent duration of two years = 58 days
Number of samples = 13
Low relative humidity (<20 RH%) – 26 days
High relative humidity (70%-80% RH) – 28 days
Low temperature (<-20°C) – 4 days

Test method : Prepare the packaging into samples of standard specifications.

The sealing strength was then measured using a digital display dedicated tensile and compression testing machine. The testing technique employed Method C; the fixture separation speed of the testing machine was 300 mm/min, the initial distance between the two fixtures was 76mm, and the sealing width was 25.4 mm.

Results: Macroscopic observation revealed that the pattern of sample packaging failure was adhesive f ailure at the sealing interface.The average peel strength of the samples is shown in the table below.

Sample Number	Average peeling strength(Ibs/in)
1	1. 82
2	1. 56
3	1. 48
4	1. 45
5	1. 41
6	1. 47
7	1. 45
8	1. 41
9	1. 44
10	1. 42
11	1. 32
12	1. 28
13	1. 57
Average	1. 45
Standard deviation	0. 19

Conclusion :

This experiment tested the packaging sealing integrity of 13 samples, with an average value of 1.45 Ibs/in and a standard deviation of 0.19. Test completion date: April 18, 2025.

Detector: Liu Chun li, Liang Yu

Accelerated Aging Test

Test basis: Refer to the methods specified in ASTM F1980-07 and ISO 11737-2: 1998.

Testing equipment: High-temperature and high-humidity aging chamber (SDWH-445), high-temperature and low-humidity aging chamber (SDWH-446), low-temperature refrigerator (SDWH-447), biochemical incubator (SDWH-309), clean bench (SDWH-149)

Test condition :

Accelerated aging (60°C), high relative humidity (RH 70-80%), low relative humidity (RH 20%), and low temperature

(<-20°C), Q₁₀=2

Experimental parameters:

Q10	TM	TRT	AAF	Desired RT	AAF
2	60°C	22. 5°C	13. 45	730Days	54 (+4)

Q₁₀:The aging factor corresponding to a temperature change of 10°C. The chemical reactions involved in material aging follow the Arrhenius reaction rate law; a 10° C change in homogeneous process temperature approximately doubles or halves the chemical reaction rate(Q₁).A conservative approach commonly used for calculating the aging factor is setting Q₁₀ equal to 2.

TM= Accelerated aging temperature (°C);

TRT= Ambient temperature (°C);

AAF(Accelerated Aging Factor) =Q₁[T-72/10.

RT:The required actual aging time;

AAT (Accelerated Aging Time) = Expected Storage Time (RT) / Accelerated Aging Factor (AAF)

Calculate accelerated aging time:

Accelerated Aging Factor (AAF)= $Q_{10}^{[(T_{AA}-T_{RT})/10]}$ = $2^{[(60-20.5)/10]}$ =13. 45

Accelerated Aging Time (AAT) = 730/13.45 = 54 (+4) days

Aging schedule:

The equivalent duration of two years = 58 days
Low relative humidity (<20 RH%) – 26 days
High relative humidity (70%-80% RH) – 28 days
Low temperature (<-20°C) – 4 days

Experimental method :

Referring to the accelerated aging test specified in ASTM F1980-07, sterilization tests were conducted on 12 individual products. After incubation at 28–32°C for 14 days, bacterial growth was observed.

Result:

Aseptic Test Result

Sample sampling ratio	1												
Culturing temperature	28-32℃												
Culture medium	SCDB												
Sample Number	Result Observation (days)												
	1	1	1	1	1	1	1	1	1	1	1	1	1
1	1	1	1	1	1	1	1	1	1	1	1	1	1
2	1	1	1	1	1	1	1	1	1	1	1	1	1
3	1	1	1	1	1	1	1	1	1	1	1	1	1
4	1	1	1	1	1	1	1	1	1	1	1	1	1
5	1	1	1	1	1	1	1	1	1	1	1	1	1
6	1	1	1	1	1	1	1	1	1	1	1	1	1
7	1	1	1	1	1	1	1	1	1	1	1	1	1
8	1	1	1	1	1	1	1	1	1	1	1	1	1
9	1	1	1	1	1	1	1	1	1	1	1	1	1
10	1	1	1	1	1	1	1	1	1	1	1	1	1
11	1	1	1	1	1	1	1	1	1	1	1	1	1
12	1	1	1	1	1	1	1	1	1	1	1	1	1
Negative control	1	1	1	1	1	1	1	1	1	1	1	1	1
Positive control	+	+	10	+	+	+	+	+	10	10	+	+	+

Note: + indicates positive; – indicates negative.

Conclusion :

After being aged and stored under the aforementioned conditions for 58 days, the sample was found to remain sterile upon testing,indicating that the packaging materials of this product exhibit good performance and sealing properties. This also demonstrates that the product can be stored for 24 months under standard environmental conditions.Test completion date: April 18,2025

Detector: Liu Chunli, Liang Yu