



中国认可
国际互认
检测
TESTING
CNAS L2954

Suzhou University
Hang Seng and Environmental Technology Institute
Final report

Report number: SDWH-M201902080-7

Refer to ASTM D 3577-09 (2015)

Perform performance testing of disposable nitrile gloves

Requester

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Test report description


1. If you have any objection to this report, please file a review application within 15 days of receiving the report.

Second, the altered test report or no special test seal is invalid.

3. There is no compiler for the test report, and the signatures of the auditor and the issuer of the test report are invalid.

4. Sample inspection is entrusted for inspection. This inspection agency is only responsible for incoming samples.

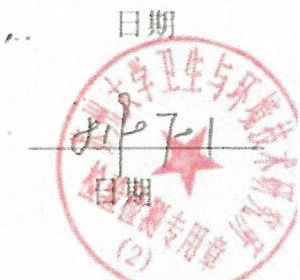
5. Without the consent of this inspection agency, this report may not be partially copied.

Test sample	
Reception date:	2019-05-27
Test plan number:	SDWH-PROTOCOL-GLP-M201902080-7
Effective date of test plan:	2019-05-31
Test operation start date:	2019-06-08
End date of test operation:	2019-06-17
Report completion date:	2019-07-01

编制： 王德衡

2019.07.01
日期

审核： 吴太梅
试验负责人



签发： 王德衡
授权签字人

2019.07.01
日期

苏州大学卫生与环境技术研究所

Quality Control Statement

The test process strictly abides by 21 CFR 58 of the US Food and Drug Administration's "Non-Clinical Research Laboratory Standards".

The exemption provisions are: 21 CFR Articles 58.105 and 58.113, sample identification and stability of the sample and plant mixture.

The quality of the ft office is responsible for overseeing the test process. The monitoring dates are shown in the table below and report to the test noble and SDWH management

监督	监督日期	数据报告试验负责人	数据报告 SDWH 管理层
试验过程	2019-06-17	2019-06-17	2019-07-01
原始数据	2019-07-01	2019-07-01	2019-07-01
报告	2019-07-01	2019-07-01	2019-07-01

质量办公室: 张 强
QA

2019-07-01
日期

1.0 Summary

The performance of the sample glove was evaluated by testing the physical dimensions and physical properties of the test sample.

The results show that under this test condition, the physical size index and physical performance index of the test sample gloves meet the requirements.

2.0 Purpose

Test the performance of the test sample gloves.

3.0 Reference Standard

Counting sampling inspection procedures-Part 1: Sampling plan for batch-by-inspection retrieval by acceptance quality limit (AQL) ISO 2859-1: 1999 Standard Specification for Surgical Nitrile Gloves ASTM D 3577-09 (2015)

4.0 Implementation specifications

ISO / IEC17025: 2005 General requirements for the competence of testing and calibration laboratories (CNAS — CL01 “Certification for the Competence of Testing and Calibration Laboratories” China National Accreditation Service for Conformity Assessment Laboratory Accreditation Registration Number: CNASL2954

RB / T 214-2017 "Evaluation of Qualification Ability of Inspection and Testing Institutions General Requirements for Inspection and Testing Institutions" China National Certification and Accreditation Administration Commission Inspection and Testing Institution Qualification Certification Number: CMA 180015144061

21 CFR 58 of the Good Food Laboratory Standards for the Clinical Research Laboratory Stem

5.0 Determination of test samples

Sample name: Disposable Nitrile Gloves

The original state of the sample: self-improvement, EO extinction

CAS number: not provided

Model: Wunan no powder noodles

Specification: 7.5

Lot number: 20190402

Sample material: rubber

Packaging quality: through origami

Properties: solid

Color: blue

Density: not provided

Verification: good

Solubility: not provided

Storage conditions: room temperature

Others: Batch: 144000 pieces. The sampling process is completed by the client.

Clinical intended use: It is suitable for surgical operations to protect patients and users from cross-infection.

The test sample information is provided by the sample commissioning unit. The entrusted unit is responsible for complying with the relevant provisions of the samples related to the GLP test.

6.0 Instruments Straightedge (SDWH639), correction validity period (2020-03-24)

Electronic digital caliper (SDWH462), correction validity period (2019-08-21)

Computerized tensile testing machine (SDWH872), the validity period of correction

(2020-03-28) Baking reed (SDWH094>, valid period of correction

(2019-12-28)

7.0 Physical size inspection

7.1 Sampling test sample gloves according to ISO2859-1, S2 inspection level. Sample code is E, AQL is 4.0

7.2 Length; measure the millimeter reading from the tip of the middle finger of 13 gloves to the outer end of the cuff as its length.

7.3 Lifting the width; measuring the millimeter reading between the glove index finger and the base of the thumb in the horizontal position of 13 gloves is its palm width.

7.4 Thickness: Measure the thickness of the middle position of the fingertips of 13 gloves and the palm of the glove • Record in millimeters.

7.5 Results:

序号	长度 (mm)	宽度 (mm)	厚度 (mm)		
			手指	手掌	袖口
1	270	100	0.20	0.23	0.13
2	268	98	0.21	0.24	0.12
3	271	99	0.21	0.23	0.13
4	267	97	0.19	0.25	0.13
5	266	98	0.20	0.23	0.14
6	267	96	0.19	0.22	0.11
7	269	98	0.22	0.24	0.12
8	270	97	0.21	0.24	0.13
9	269	98	0.23	0.23	0.14
10	270	97	0.22	0.25	0.14
11	268	98	0.21	0.23	0.13
12	267	98	0.22	0.24	0.13
13	265	98	0.20	0.23	0.12
标准要求	≥265	95±6	≥0.10		
结论	合格	合格	合格	合格	合格

7.6 Conclusion: Under this test condition, the test result is acceptable.

8.0 Physical performance testing

8.1 Take 13 samples of gloves and put them in the test environment at a temperature of 23 ± 2X: relative humidity of 50 ± 5% for at least 24 hours.

8,2 Cut the C-shaped dumbbell-shaped test piece from the hand food and place it on the jig of the tension machine, adjust the weight to make the force even.

8.3 Start the tension machine. The sample with a jig separation rate of 500 ± 50 nun / min is broken to fracture at normal preparation strength.

8.4 Calculate tensile strength and final elongation, f

8.5 Take 13 samples of 7.5 "gloves and place them at 70 ± 2 °C for 166 ± 2h, then repeat the test.

8.6 Judgment criteria:

检测项目	老化前			老化后	
	拉伸强度	最终伸长率	500%伸长率的拉伸强度	拉伸强度	最终伸长率
标准要求	≥24MPa	≥750%	≥5.5MPa	≥18 MPa	≥560%
检验水平	S-2				
接受质量限	4.0				
样本量字码	E				
可接受不符合样品	≤1	≤1	≤1	≤1	≤1

8.7 结果:

序号	老化前			老化后	
	拉伸强度 (MPa)	最终伸长率 (%)	500%伸长率的 拉伸强度 (MPa)	拉伸强度 (MPa)	最终伸长率 (%)
1	56.77	1245	9.17	38.30	1106
2	51.89	1504	5.63	42.18	1322
3	44.15	1458	8.97	51.03	1526
4	47.30	1554	6.53	48.04	1436
5	54.77	1153	10.07	50.76	1110
6	53.32	1275	15.87	41.74	1172
7	40.15	1230	13.50	56.49	1303
8	46.35	1000	14.10	42.63	1402
9	48.52	1384	16.17	50.58	1386
10	52.90	1547	6.87	53.93	1328
11	40.51	1166	7.07	43.86	1226
12	41.99	1068	10.67	45.00	1294
13	52.27	1253	15.97	51.40	1434
结论	合格	合格	合格	合格	合格

8.8 Conclusion: Under this test condition, the test result is acceptable.

9.0 Conclusion

Under this test condition, the physical size index and physical performance index of the test sample meet the requirements.

10.0 record storage

All original data and records related to this test are saved in the designated SDWH archive file.

11.0 Confidentiality Agreement

After signing the inspection commission contract, both parties accept the confidentiality agreement.