

Report No.: **168488221a 001** Page 1 of 4

Client: **SHANDONG SHANGWEI MEDICAL PRODUCTS CO., LTD.**

Contact Information: North Road, Fumin Avenue, Qinghe Street, Caoxian, Heze City,
Shandong Province, P. R. China

Manufacturer's name: **SHANDONG SHANGWEI MEDICAL PRODUCTS CO., LTD.**

Identification/
Model No(s): DISPOSABLE VINYL GLOVE, POWDERED, NON-STERILE

Sample obtaining method: Sending by customer

Condition at delivery: Test item complete and undamaged.

Sample Receiving date: 2024-06-06

Testing Period: 2024-06-13 to 2024-06-19

Place of testing: Chemical laboratory Shenzhen

Test Specification:

Customer's requirement:

1. Biocides (Biological Active Products) -1,2-Benylisothiazolin-3-one (BI)

Test result:

Please refer to result
page

Other information:

(1) Information provided by customer:

Country of Origin: Shandong Shangwei Medical Products Co., Ltd.

For and on behalf of
TÜV Rheinland (Shenzhen) Co., Ltd.



2024-06-20

Lucy Wang / Senior Technical Executive

Date

Name/Position

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed.
This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.
"Decision Rule" document announced in our website (<https://www.tuv.com/landingpage/en/qm-gcn/>) describes the statement of conformity and its rule of enforcement for test results are applicable throughout this test report.

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Material List:

Item: DISPOSABLE VINYL GLOVE, POWDERED, NON-STERILE

Material No.	Material	Color	Location
M001	Plastic	Translucent	Disposable Vinyl glove, powdered, non-sterile

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1. Biocides (Biological Active Products) -1,2-Benylisothiazolin-3-one (BI)

Test Method: Organic solvent extraction, LC-MS/MS analysis

Test result

Test No.	Material No.	Test Parameter	CAS No.	Unit	RL	Test Result
T001	M001	1,2-Benylisothiazolin-3-one (BI)	2634-33-5	mg/kg	10	< RL

Abbreviation: < denotes less than
RL = Reporting Limit
mg/kg = milligram per kilogram

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Sample Photo



- END -

Test Report

No.: TSNHL24001172801

Date: Jun 14, 2024

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Client Name: SHANDONG SHANGWEI MEDICAL PRODUCTS CO.,LTD

Client Address: NORTH ROAD, FUMIN AVENUE, QINGHE STREET, CAO XIAN, HEZE CITY, 274400,
SHANDONG PROVINCE, P.R.CHINA

Sample Description: Disposable Examination Vinyl Glove, Powder-free, Non-sterile

Item No.: Medium

The above sample(s) and information were provided by the client.

SGS No.: TJHL2406004915CW (QDHL2405007704CW)

Sample Receiving Date: Jun 07, 2024

Testing Period: Jun 07, 2024 ~ Jun 14, 2024

Test Requested: Select test(s) as requested by the client.

Testing Performed: Follow selected test(s) as requested by client.

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.Patrick Kou 寇怀江
Approved Signatory

Scan to see the report

TSNHL24001172801
Verification:
check.sgsline.com.cn

This report is English version of TSNHL24001172802.



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t (86-22) 65288000www.sgs.com.cn
sgs.china@sgs.com

	Test Requirement	Comment
1	GB 4806.7-2023 - Decolor Test	Pass
2	GB 4806.7-2023 - Sensory(Appearance: Normal color,no smell,no impurity)	Pass
3	GB 4806.7-2023 - Sensory(Marinate: No turbidity,no precipitate,no smell,or other sensory deterioration)	Pass
4	GB 4806.7-2023 - Overall Migration	Pass
5	GB 4806.7-2023 - Consumption of Potassium Permanganate	Pass
6	GB 4806.7-2023 - Heavy metal (as Pb)	Pass
7	GB 4806.7-2023 - Specific migration of primary aromatic amine	Pass



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Chemical Laboratory

SGS Mansion, No.41, The 5th Avenue TEDA, Tianjin, China 300457
中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457

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Test Result(s):

Test Part Description:

SN ID	Sample No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	A1	TSN24-0011728-0001.C001	white plastic gloves	PVC

Remarks:

- (1) mg/dm² = milligram per square decimeter
 mg/inch² = milligram per square inches
 µg/cm² = microgram per square centimeter
 mg/L = milligram per litre
 mg/kg = milligram per kilogram
- (2) °C = degree Celsius
 °F = degree Fahrenheit
- (3) <= less than
- (4) RL = Reporting Limit
- (5) ND = Not Detected (< RL).

The ratio of surface area to volume

Sample No	Overall Migration	Specific Migration
A1	6.0 dm ² /kg	6.0 dm ² /kg

GB 4806.7-2023 - Decolor Test

Test Method: GB 31604.7-2023.

Test Item(s)	Limit	A1
The Color of Absorbent Cotton		
4% Acetic Acid(V/V)	Negative	Negative
Decolor Test in Marinade		
4% Acetic Acid(V/V)	Negative	Negative
Comment		Pass

GB 4806.7-2023 - Overall Migration

Test Method: GB 31604.8-2021 part 1.

Simulant used	No of Migration	Test Condition	Limit	Unit(s)	RL	A1	Comment
4% Acetic Acid(V/V)	1 st	40°C, 0.5 hr	10	mg/dm ²	3.0	ND	Pass

Notes:

- (1) Test condition & simulant were specified by client.



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Test Report

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GB 4806.7-2023 - Consumption of Potassium Permanganate

Test Method: GB 31604.2-2016.

Simulant used	No of Migration	Test Condition	Limit	Unit(s)	RL	A1	Comment
DI water	1 st	60°C, 2 hrs	10	mg/kg	1	2.2	Pass

GB 4806.7-2023 - Heavy metal (as Pb)

Test Method: GB 31604.9-2016 method I.

Simulant used	No of Migration	Test Condition	Limit	Unit(s)	A1	Comment
4% Acetic Acid(V/V)	1 st	60°C, 2 hrs	1	mg/kg	<1	Pass

GB 4806.7-2023 - Specific migration of primary aromatic amine

Test Method: GB 31604.52-2021.

Simulant	Test Condition	
	A1	
4% Acetic Acid(V/V)	40°C, 0.5 hr	

Test Item(s)	CAS No.	Limit	Unit(s)	RL	A1
4% Acetic Acid(V/V)					
Migration times					First
1,4-Phenylenediamine	106-50-3	-	mg/kg	0.003	ND
1,3-Phenylenediamine	108-45-2	-	mg/kg	0.003	ND
2,4-Toluenediamine (2,4-TDA)	95-80-7	-	mg/kg	0.003	ND
4,4'-Diaminodiphenyl ether	101-80-4	-	mg/kg	0.003	ND
Benzidine	92-87-5	-	mg/kg	0.003	ND
4,4'-Methylenedianiline	101-77-9	-	mg/kg	0.003	ND
Aniline	62-53-3	-	mg/kg	0.003	ND
o-Anisidine	90-04-0	-	mg/kg	0.003	ND
o-Toluidine	95-53-4	-	mg/kg	0.003	ND
4,4'-Methylenedi-o-toluidine	838-88-0	-	mg/kg	0.003	ND
3,3'-Dimethoxybenzidine	119-90-4	-	mg/kg	0.003	ND
3,3'-Dimethylbenzidine	119-93-7	-	mg/kg	0.003	ND
2,6-Dimethylaniline (2,6-DMA)	87-62-7	-	mg/kg	0.003	ND
2,4'-Diaminodiphenylmethane	1208-52-2	-	mg/kg	0.003	ND
4-Methoxy-m-phenylenediamine	615-05-4	-	mg/kg	0.003	ND
2-Methoxy-5-methylaniline	120-71-8	-	mg/kg	0.003	ND
2,4,5-Trimethylaniline	137-17-7	-	mg/kg	0.003	ND
4,4'-Thiodianiline	139-65-1	-	mg/kg	0.003	ND
4-Chloroaniline	106-47-8	-	mg/kg	0.003	ND
2,4-Dimethylaniline (2,4-DMA)	95-68-1	-	mg/kg	0.003	ND



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 Chemical Laboratory

SGS Mansion, No.41, The 5th Avenue TEDA, Tianjin, China 300457
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Test Report

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Test Item(s)	CAS No.	Limit	Unit(s)	RL	A1
2-Naphthylamine	91-59-8	-	mg/kg	0.003	ND
2,2'-Diaminodiphenylmethane	6582-52-1	-	mg/kg	0.003	ND
4-Aminobiphenyl	92-67-1	-	mg/kg	0.003	ND
4-Chloro-o-toluidine	95-69-2	-	mg/kg	0.003	ND
2-Amino-4-nitrotoluene	99-55-8	-	mg/kg	0.003	ND
3,3'-Dichlorobenzidine	91-94-1	-	mg/kg	0.003	ND
4-Amino azobenzene	60-09-3	-	mg/kg	0.003	ND
4,4'-Methylene-bis-(2-chloro-aniline)	101-14-4	-	mg/kg	0.003	ND
o-Aminoazotoluene	97-56-3	-	mg/kg	0.003	ND
Total	-	ND	mg/kg	0.01	ND
Comment					Pass

Notes:

(1) Test condition & simulant were specified by client.

Unless otherwise stated, the decision rule for conformity reporting is based on Binary Statement for Simple Acceptance Rule (w=0) stated in ILAC-G8:09/2019.



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Test Report

No.: TSNHL24001172801

Date: Jun 14, 2024

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Sample Photo:



SGS authenticate the photo on original report only
*** End of Report ***

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中国认可
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检测
TESTING
CNAS L3129

Testing Report



Report No.: HQ2430601574-2

Applicant: Shandong Shangwei Medical Products Co.,Ltd.
North Road, Fumin Avenue, Qinghe Street, Caoxian, Heze
City ,274400, Shandong Province, P.R. China

Contact: /

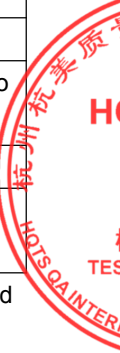
Overall Rating:	
Data	<input type="checkbox"/>
Satisfactory	<input checked="" type="checkbox"/>
Unsatisfactory	<input type="checkbox"/>
Others, See Detail Enclosed	<input type="checkbox"/>

Sample Information



Client:	/
Supplier:	Shandong Shangwei Medical Products Co.,Ltd.
Factory:	Shandong Shangwei Medical Products Co.,Ltd.
Item No.:	Medium
Sample Description:	Disposable Vinyl Glove
PO No.:	20240624
Sample Submitted:	3pcs in good condition were provided by applicant
Received Date:	Jun.27,2024
Testing Period:	Jun.27,2024 to Jul.08,2024
Testing Standard:	Selected tests as requested by applicants, details refer to following pages.
Service Location:	Hangzhou
Remark:	This report is the English version of test report NO. HQ2430601574-1 issued on Jul.08,2024

*****To be Continued





中国认可
国际互认
检测
TESTING
CNAS L3129

Testing Report



Report No.: HQ2430601574-2

Testing Summary of Tested Component on Submitted Sample:

1 Microbiological

Pass

*****To be Continued

HQTS QA International Services Co., Ltd.



Approved by

Nayel Luo

Issued Date: 2024-07-08





中国认可
国际互认
检测
TESTING
CNAS L3129

Testing Report



Report No.: HQ2430601574-2

1 Microbiological

GB 15979-2002

Tested Component	Disposable Vinyl Glove			
Tested Item	Tested Method	Requirement (cfu/g)	Results (cfu/g)	Comment
Aerobic Bacterial Count	Hygienic standard for disposable sanitary products for GB 15979-2002 The Microbiological tested annex B	≤200	Not Detected	Pass
Molds and Yeast Count	Hygienic standard for disposable sanitary products for GB 15979-2002 The Microbiological tested annex B	≤100	Not Detected	Pass
Thermotolerant Coliform Bacteria	Hygienic standard for disposable sanitary products for GB 15979-2002 The Microbiological tested annex B	Not Detected	Not Detected	Pass
Pseudomonas Aeruginosa	Hygienic standard for disposable sanitary products for GB 15979-2002 The Microbiological tested annex B	Not Detected	Not Detected	Pass
Staphylococcus Aureus	Hygienic standard for disposable sanitary products for GB 15979-2002 The Microbiological tested annex B	Not Detected	Not Detected	Pass
Hemolytic streptococcus	Hygienic standard for disposable sanitary products for GB 15979-2002 The Microbiological tested annex B	Not Detected	Not Detected	Pass



*****End of Report

Certificate


Quality Management System EN ISO 13485:2016

Registration No.	SX 2098014-1
Certificate Holder	Shandong Shangwei Medical Products Co., Ltd. North of Fumin Avenue East Section, Qinghe Sub-district Office, Cao County, Heze City 274400 Shandong P.R. China
Scope	Manufacture and Distribution of Disposable Polyvinyl Chloride Examination Gloves, Disposable Polyvinyl Chloride and Nitrile Synthetic Examination Gloves, Disposable Nitrile Examination Gloves, Disposable Medical Face masks, Surgical Face masks, Medical Protective Face Masks

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.	190141596-110
Effective date	2023-06-28
Expiry date	2025-02-13
Issue date	2023-06-28
Replaces certificate SX 2098014-1 issued 2021-12-14	

This certificate can be validated on <https://www.certipedia.com>


Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Certificate

Quality Management System EN ISO 13485:2016

Registration No. SX 2098014-1
Certificate Holder Shandong Shangwei Medical Products Co., Ltd.
North of Fumin Avenue East Section,
Qinghe Sub-district Office,
Cao County, Heze City
274400 Shandong
P.R. China

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Shandong Shangwei Medical Products Co., Ltd. North of Fumin Avenue East Section, Qinghe Sub-district Office, Cao County, Heze City 274400 Shandong P.R. China	Manufacture and Distribution of Disposable Polyvinyl Chloride Examination Gloves, Disposable Polyvinyl Chloride and Nitrile Synthetic Examination Gloves, Disposable Nitrile Examination Gloves
/02	c/o Shandong Shangwei Medical Products Co., Ltd. West of Cross of Qinghe North Road and Songhuajiang Road, Cao County, Heze City, 274400 Shandong P.R. China	Manufacture and Distribution of Disposable Medical Face masks, Surgical Face masks, Medical Protective Face Masks

Report No. 190141596-110
Effective date 2023-06-28
Expiry date 2025-02-13
Issue date 2023-06-28



Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 2132982**

Certificate Holder: **Liaoning Shangwei Medical Products Co., Ltd.**
Unified Social Credit Code: 91211281MA10J5KR41
Registration Address: North West of Xinlixian,
Quanyangou Village, Xiaonan Town, Diaobingshan,
Tieling, 112700 Liaoning, P. R. China
Operation Address: same as above

Scope: **Manufacture and Sales of Polyvinyl Chloride / Nitrile Gloves;
Sales of Face Masks**

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2024-09-09 until 2027-09-08.
It remains valid subject to satisfactory surveillance audits.
First certification 2021
This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>

2024-06-17



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Authorized responsible office: TÜV Rheinland China Ltd., Room 301, 3F and Room 1203, 12F, Building 4, No. 15, Ronghua South Road, Beijing Economic-Technological Development Area, Beijing (Yizhuang group in high-end industrial area of Beijing Pilot Free Trade Zone), 100176, P. R. China

Registration Number has been assigned – Your registration number is 3015477649

发件人: CDRH Registration and Listing<reglist@CDRH.FDA.GOV>

时 间: 2020 年 4 月 11 日(星期六) 凌晨 2:21

收件人: cathy@zgjxyjt.com<cathy@zgjxyjt.com>

Dear Owner/Operator and/or Official Correspondent:

This email is being sent to inform you that a registration number has been assigned to the following establishment:

SHANDONG SHANGWEI MEDICAL PRODUCTS CO.,LTD
NORTH ROAD, FUMIN AVENUE,QINGHE STREET,
CAOXIAN COUNTY
HEZE CITY
CHINA 274400

Registration Number: 3015477649

Owner Operator Number: 10064517

If you have any questions or need assistance, please contact CDRH Registration and Listing Office by email at reglist@cdrh.fda.gov.

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Center for Devices and Radiological Health
U.S. Food and Drug Administration

Tel: 301-796-7400, Option 1

Email: reglist@cdrh.fda.gov

2 个普通附件

Header.jpg (45.26K)

SignatureBlockLogo.png (6.24K)