

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/ DISPOSABLE VINYL GLOVE, POWDERED, NON-STERILE

Model No(s):

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: Test result:

Customer's requirement:

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



Test Report No.: 168488221a 001

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 -



General Terms and Conditions of Business of TÜV Rheinland in Greater China

- Scope
 These General Terms and Conditions of Business of TUV Rheinland in Greater China ("GTCB") is made between the client and one or more member entities of TUV Rheinland in Greater China is applicable as the case may be ("I'UV Rheinland"). The Greater China hereof refers to the regions within the territories of China. The Client hereof includes:

 a natural person capable to form laggly binding contracts under the applicable laws who concludes the contract not for the purpose of a daily use.

 The following terms and conditions of proceedings of the contract under the applicable law. The following terms and conditions of provisions the vision and conditions of the contract under the applicable two. The following terms and conditions of the client daily strip calcillary services and similar services as well as an activate services information, deliveries and similar services as well as an activate services information, deliveries and similar services as well as an activate services and services and services are services as well as an activate services and services and services are services as well as an activate services and services and services are services as well as an activate services and services are activated as the contract even if TUV Rheinland does not explainly object to them. In the context of an ongoing business relationship with the client, this CTGB shall also apply to future contracts with the client without TUV Rheinland having to refer to them separately in each individual case.
- (ii)
- 13

Unless otherwise agreed, all quotations submitted by TÜV Rheinland can be changed by TÜV Rheinland without notice prior to its acceptance and confirmation by the other party.

Coming into effect and duration of contracts

- Coming into effect and duration of contracts

 The contract shall come into effect for the agreed terms upon the quotation letter of TÜV.

 Rhenland or a separate contractual document being signed by both contracting parties, or upon
 the works requested by the client being carried out by TÜV. Rheinland if the ident instructs TÜV.

 Rheinland without receiving a quotation from TÜV Rheinland (quotation), TÜV Rheinland without receiving a quotation from TÜV Rheinland (quotation), TÜV Rheinland without receiving a quotation from TÜV Rheinland (quotation), TÜV Rheinland is, in its sole discretion, erfeitled to accept the order by giving written notice of such acceptance (including notice sent via effectronic means) or by performing the requested services.

 The contract term starts upon the coming into effect of the contract in sociodance with article 3.1 and shall continue for the term agreed in the contract.

 If the contract provides for an existention of the coloration term, the contract term will be extended the contract in the contract term.
- 3.3

- The scope and type of the services to be provided by TÜV Rheinland shall be specified in the contractually agreed service scope of TÜV Rheinland by both parties. If no such separate service scope of TÜV Rheinland ostaits, hen the written confirmation of order by TÜV Rheinland ostaits, hen the written confirmation of order by TÜV Rheinland ostaits, hen the written confirmation of order by TÜV Rheinland ostaits, hen the service description (e.g., checking the correctness and functionality of parts, products, proprocesses, installations, organizations not Island in the service description, as well as the intended use and application of such) are not owed. In particular, no responsibility is assumed for the design, selection of materials, construction or intended use of an examined part product, process or plant, unless this is expressly stated in the order.
- 4.3
- The agreed services shall be performed in compliance with the regulature is in a contract is entered into.

 TÜV Rheinland is entitled to determine, in its sole discretion, the method and nature of the assessment unbest scherwise agreed in writing or if mandatory provisions require a specific procedure to be followed.

 On execution of the Nette shall be no simultaneous assumption of any guarantee of the On execution of the willy) and working order of either tested or exemined parts nor of the installation as a whole and its upstream and/or downstream processes, organisations, use and application in accordance with regulations, nor of the systems on which the installation is based in particular. TÜV Rheinland shall assume no responsibility for the construction, selection of materials and assembly of installations examined, nor for the use and application in accordance with regulations, unless these questions are expressly covered by the contract.

- in particular, TÜV Rheinland shall assume no responsibility for the construction, selection of materials and assembly of installations examined, not for their use and application in accordance with requisitions, unless these questions are expressly covered by the contract.

 In the case of inspection work, TÜV Rheinland shall not be responsible for the accuracy or checking of the safety programmes or safety regulations on which the inspections are based, responsible to the safety programmes or safety regulations on which the inspections are based, responsible to the safety programmes or safety regulations on which the inspections are based, responsible to the contract, with a written notice to the client, TÜV Rheinland shall be entitled to additional renumeration for resulting additional expenses.

 The services to be provided by TÜV Rheinland under the contract are agreed exclusively with the contract are services to be provided by TÜV Rheinland under the contract are agreed exclusively with the contract and approximate the contract are services. This also applies if the client passes on work results in full or in extracts to that parties in accordance with clause 11. A provided the contract and the center services are not directly provided by rule (provided by any contract and the direct services actually to be provided by our company in but services are not directly provided by rule of provided and contract and the direct services actually to be provided by our company in the service provided by any other third appring least and the contract, the client hereby agrees that TÜV Rheinland will provide the client as again for such relevant services in order to achieve the purpose of the contract, the client hereby agrees that

- 5.5
- Performance periods/dates of performance are based on estimates of the work involved which are prepared in line with the details provided by the client. They shall only be binding fleeing confirmed as binding by TUV Rehination to writing, shall not commence until the Archies 1.1 and 5.2 also apply, even whost or spread to the periods shall not commence until the Archies 5.1 and 5.2 also apply, even whost or express approval by the client, to all extensions of agreed periods/dates of performance not caused by TUV Rehelman. TUV Rehination and or responsible for a delay in performance, in particular if the client has not input to the periods of t
- to resume performance.

 The client is obliged to comply with legal, officially prescribed and/or by the accreditor prescribed deadlines, it is the client's obliged to comply with legal, afficially prescribed and/or by the accreditor prescribed deadlines. It is the client's responsibility to agree on performance dates with TUV Rheinland, which enable the client to comply with the legal and/or officially prescribed deadlines. TUV Rheinland assumes no responsibility in this respect unless TUV Rheinland expressly agreed in writing specifically stating that enumpting the deadlines is the contractual obligation of TUV.

- The client shall guarantee that all cooperation required on its part, its agents or third parties will be provided in good time and at no cost to $T\bar{U}V$ Rheinland. 6.1
- Design documents, supplies, suxiliary staff, etc. necessary for performance of the services shall be made available free of charge by the client. Moreover, collaborative action of the client must be undertaken in accordance with legal provisions, standards, safety regulations and accident prevention instructions. And the client represents and variants that:

- b) the product, service or management system to be certified complies with applicable laws and regulations; and
- it doesn't have any illegal and dishonest behaviours or is not included in the list of Enterprises with Serious Illegal and Dishonest Acts of People's Republic of China.
- If the client breaches the aforesaid representations and warranties, TÜV Rheinland is entitled to i) immediately terminate the contract/order without prior notice; and ii) withdraw the issued testing report/centificates
- The client shall bear any additional cost incurred on account of work having to be redone or being delayed as a result of late, incorrect or incomplete information provided by or lack of proper cooperation from the client. Even where a fixed or maximum price is agreed, TÜV Rheinland shall be entitled to charge extra fees for such additional expense.

- 7.1
- If the scope of performance is not laid down in writing when the order is placed, invoicing shall be based on costs actually incurred. If no price is sagreed in writing, invoicing shall be made in accordance with the price list of TUV Phenianda valid at the time of performance. Unless otherwise agreed, work shall be invoiced according to the progress of the work. If the execution of an order actuation over more than one month and the value of the contract or the agreed fixed price exceeds £2,500.00 or equivalent value in local currency. TUV Rheinland may demand payments on account or in installments.

- All invoice amounts shall be due for payment within 30 days of the invoice date without deduction on receipt of the invoice. No discounts and rebates shall be granted. Payments shall be made to the basis, account of TUV Rhenland as indicated on the invoice, stating the invoice and client numbers. Stating the invoice and client numbers. Stating the invoice and client numbers. Stating the invoice and client numbers of the properties of the properties of the properties of the properties of the publicy amounted by a reputable commercial bank in the country where TUV Rheinland is located. At the same time, TUV Rheinland reserves the right to claim further demanges.
- applicable short term loan interest fave puocus princeres up a reposeer connected and the country where TUV Rheisland is located. At the same time, TUV Rheinland reserves the right the country where the term of the invoice despite being granted a reasonable grace period. TUV Rheinland shall be entitled to cancel the contract, withdraw the certificate, claim damages for non-performance and refuse to continue performance of the contract. The provisions set forth in article & I shall also apply in cases involving returned cheques, cessation of payment, commencement of insolvency proceedings against the claimst assets or contract to the contract of the contract of the contract of payment, commencement of insolvency proceedings against the claimst assets or contract of the contract of payment, commencement of insolvency proceedings against the claimst assets or contract of the contract
- ets.
 ections to the invoices of TÜV Rheinland shall be submitted in writing within two weeks of epit of the invoice.

TÜV Rheinland shall be entitled to demand appropriate advance payments. TÜV Rheinland shall be entitled to raise its fees at the beginning of a month if overheads and/or purchase costs have heroteader. In this case, TÜV Rheinland shall notify the client in writing of the upper purchase to the proper purchase the proper purc

Only legally established and undisputed claims may be offset against claims by TÜV Rheinland. TÜV Rheinland shall have the right at all times to setoff any amount due or payable by the client including but not limited to setoff against any less goal by the client under any contracts agreement and or orders/quotations reached with TÜV Rheinland.

- 9.1
- Any part of the work result ordered which is complete in itself may be presented by TÜV Rheniand for acceptance as an instalment. The client shall be obliged to accept it immediately. If acceptance is required or contractually agreed in an individual case, this shall be deemed to have taken place two (2) weeks after completion and handover of the work, unless the client retures acceptance within this period stating at least one unfunderable tracked or contract by TÜV.
- Rheinland.

 The client is not entitled to refuse acceptance due to insignificant breach of contract by TÜV
 Rheinland. 9.3
- Rheinland. If acceptance is excluded according to the nature of the work performance of TÜV Rheinland, the completion of the work shall take its place. During the Follow-Audit stage, if the client was unable to make use of the time windows provided for within the scope of a certification procedure for auditing/performance by TÜV Rheinland and the certificate is therefore to be withdraw (e.g. performance of surveillance audits), or if the client certification promote in the certification procedure of surveillance audits), or if the client certification shallow of the certification promote and the certification procedure of surveillance audits), or if the client certification is made and the certification of the cer
- Rhehland has incurred no damage whatsoever or usy a wannounce, ..., above lump sum, ar as the client has undertaken in the contract to accept services, TUV Rheinland shall also be entitled to charge lump-sum damages in the amount of 10% of the order amount as compensation for expenses if the service is not called within one year after the order has been placed. The client reserves the right to prove that the TUV Rheinland has incurred no damage whatsoever or only a considerably lower damage than the above mentioned lump sum.

- dentiality

 For the purpose of these terms and conditions, "confidential information" means all know-how, trade secrets, documents, images, drawings, expertise, information, dais, test results, teports, and secrets, documents, images, drawings, expertise, information, dais, test results, teports, and marketing techniques and materials, tangible or intangible, that are supplied, transferred or indevise disclosed by one Party (the "disclosing party") to the other Party (the "receiving party"), in writing or orally, in printed or electronic format. Confidential information is expressly not the data and know-how collected, complete or otherwise disclosined by TD (Febrahard flore)-personal confidential information is expressly not the data and know-how collected, complete or otherwise disclosined by TD (Febrahard flore)-personal confidential information is expressly not the data and know-how collected, complete or otherwise disclosined by TD (Febrahard flore)-personal confidential information is disclosed party. The personal confidential information is disclosed orally, the receiving party, the provision of services. 10.2 The disclosing party shall mark all conceiving party. The same applies to confidential information is advance and the disclosing party shall confirm in writing the confidential protein the receiving party. The same applies to confidential information transmitted by e-mail. If confidential information is disclosed orally, the receiving party platform and/or system (e.g. Wechst, etc. Unauthorized by TÜV Pheinland; by the disclosing party shall confirm in writing the confidential information to TÜV Pheinland. Instead, the client shall avoid unique gray third party platform and/or system (e.g. Wechst, etc. Unauthorized by TÜV Pheinland; altornation to compare and of TÜV Pheinland. Instead, the client shall avoid unique gray third party platform and/or system (e.g. Wechst, etc. Unauthorized by TÜV Pheinland; by the disclosing party transmits or otherwise discloses to the caused by the advanced and which
- 10.3
- 10.5 a)
- 10.7

11.1

- TÜV Rheinland shall retain all exclusive copyrights in the reports, expert reports/opinions, test reports/results, results, calculations, presentations etc. prepared by TÜV Rheinland, unless otherwise agreed by the parties in a separate agreement. As the owner of the copyrights, TÜV Rheinland is free to grant others the right to use the work results for individual or all types of use
- Rhehinal is free to grant others the right to use the work results for individual or all types of use (right of use). The client receives a simple, unlimited, non-transferable, non-sublicensable right of use to the contents of the work results produced within the scope of the contract, unless otherwise agreed by the parties in a separate agreement. The client may only use such reports, export reports/opinions, test apports/results, results calculations, presentations etc. prepared within the scope of the contract for the contractually agreed purpose. subject to Mil proyment of the renumeration agreed in tenuous left of clause 11.2 of the GTCB is subject to Mil proyment of the renumeration agreed in tenuous left of the Client may only pass on the work results in Unless TUV Rheinland has given its provivation correct to the partial passing on of work results.
- 11.4
- work results in full unless 1UV Rhenland has given its pror written consent to the partial passing on I work results in Societies and public exploration of work results for schedinging purposes or any further use of Arry publication the exploration between the soope regulated in clause 11.2, and any apartial or the introduction of TUV Rhenland need the prior written approval of TUV Rhenland in each individual cases. Besides, the client ensures that the aforesaid use shall comply with relevant applicable laws, regulators and relevant rules (including but not limited to specific applicable testing and certification rules, etc.). TUV Rhenland may revoke a once given approval according to clause 11.5 at any time without stating reasons. In this case, the client is colleged to stop the transfer of the work results immediately afth own expense and, as first any possible, to whichersy publications not exist exist. The consent of TUV Rhenland to publication of the work results intent to see the corporate logo, corporate design or reschederfication mask of TUV Rhenland.

Liability of TÜV Rheinland 12.1

- Liability of TÜV Rheinland

 Irraspective of the legal basis, to the fullest extent permitted by applicable law, in the event of a breach of contractual obligations or lord, the liability of TÜV Rheinland for all damages, bases and reimbursament of expenses caused by TÜV Rheinland, its legal representatives and/or employees shall be limited to: (i) in the case of a contract with a fixed overall feet, these times the representatives are considered to the case of a contract expressity charged on a time and material basis, a maximum of 20,000 Euror or squivalent amount in local currency; and (by) in the case of a familieror, and a fixed provides for the possibility of placing individual orders, three times of Nowthatandrian places are considered to the case of a contract expressity of placing individual orders, there is the contract case of the contract of th

When passing on the services provided by TÜV Rheinland or parts thereof to third parties in Greater China or other regions, the client must comply with the respectively applicable regulations of national and international export control law. The performance of a contract with the client is subject to the provisio that there are no obstacles to performance due to national or international foreign trade legislations or embargos and/or the performance due to national or international foreign trade legislations or embargos and/or the performance due to national or international foreign trade legislations or embargos and/or the performance of the national or international foreign trade legislations or embargos and/or the performance of the national or the performance of the performance of the national performance of the national performance of the performance of the national performance of the national performance of the performance of 13.1

sanctions. In the event of a violation, TÜV Rheinland shall be entitled to terminate the contract with immediate effect and the client shall compensate for the losses incured thereof by TÜV Rheinland.

Data protection notice

The client understands and agrees that TÜV Rheinland processes personal data (including but not limited to penceal information) of the client and its related parties (including but not limited to the client and its related parties (including but not limited to the client and its related parties (including but not limited to the client client or process the personal data that the client collected or processes day itself and transferred to TÜV Rheinland. For certain services, we may also process sensitive personal data. TÜV Rheinland will use and process the data in accordance with the relavant legal basis. It any personal data has to be disclosed or transferred to any hird party or any overseas party outde of the data has be disclosed or transferred to any hird party or any overseas party outde of the data has be disclosed or transferred to any hird party or any overseas party outde of the data has be disclosed or transferred to any hird party or any overseas party outde of the data has be disclosed or transferred to any hird party or any overseas party outde of the data has be disclosed or transferred to any hird party or any overseas party outde of the data has be disclosed or transferred to any hird party or any overseas party outde of the data has be disclosed or transferred to any hird party or any overseas party outde of the data has been depended to the data of the personal data. The personal subject to the data subject. TÜV Rheinland will early outdened to the processing plant the right to revoke their consent at any time with effect for the future, as well as the right to file a complaint with the content of the processing plant and protection information. You can contact the Group Data Protection Officer of TÜV Rheinland W. Jernal at datasprotection officer, and Group post at the following address: TÜV Rheinland W. Jernal and data protection officers of TÜV Rheinland W. Jernal and Jernal data for TÜV Rheinland W. Jernal at datasprotection Officer, Am Grauen Stein, \$1105 Cologne,

- 15.2
- tion of test material and documentation

 The test samples submitted by the client to TÜV Rheinland for testing will be scrapped following testing or will be returned to the client at the client's experies. The only exceptions are test stating requirement with the client.

 In storage or the basis of sistutions requirement with the client in storage on the basis of sistutions regulations or of another agreement with the client.

 Charges apply if the test samples are stored at the premises of TÜV Rheinland. The cost of placing a test sample into storage will be disclosed to the client in the quotation. If reference samples or documentations are given to the client to be placed in storage at their premises, the reference samples or documentations are given to the client to be placed in storage at their premises, the reference samples ander documentation, any liability claims for material and pecuniary damage resulting from the respective testing and certification that is brought forward by the client against TUV Rheinland as allow olded.

 The retention period for the documentation shall be 10 (ten) years after the expiry of the test mark and GS mat contributions. The cost of the handover and dispatch of the test samples for storage on the client's premises are more by the client against will be liable for the loss of test samples or reference samples from the laboratories or warehouses of TUV Rheinland only in case of gross negligence.

- Ination of the contract

 Nowthstanding clause 3.3 of the GTCB, TÜV Rheinland and the client are entitled to terminate the contract in set entitley or, in the case of services combined in one contract, each of the combined parts of the contract in set entitley or, in the case of services combined in one contract, each of the combined parts of the contract individually and independently of the contract, each of the combined parts of the contract individually and independently of the contract, each of the contract with six (8) months individually and independently of the contract individually and to a loss or a suspension of its accreditation or notification.

 For good causes, TÜV Rheinland may consider giving a written notes to the client to terminate the contract without bearing any liabilities and the client shall pay the relevant service less for the contract without bearing any liabilities and the client shall pay the relevant service less for the services provided by TÜV Rheinland due to the termination due to the contract. The discression as the conditions within the company which are relevant for cordification or size of such changes;

 b) the client does not immediately notly TÜV Rheinland or changes in the conditions within the company which are relevant for cordification mark or uses it is violation of the contract.

 b) the client misuses the certificate or certification mark or uses it is violation of the contract.

 c) a substantial deterioration of the financial circumstances of the client occurs and as a result the payment claims of TÜV Rheinland under the contract are considerably endangered and TÜV Rheinland cannot reasonably be expected to contribute on the contract and considerably endangered and TÜV Rheinland cannot cannot be expected to contribute the contract and considerably interest and as a result the payment claims of TÜV Rheinland cannot cannot be expected to contribute on the contract of the client nearest and the entities of a human cannot endange applicable to TÜV Rheinland and TÜV Rhei

- Majoura*

 Majour

- hip The Parties are bound to perform their contractual duties even if events have rendered performance more onerous than could reasonably have been anticipated at the time of the conclusion of the
- The Parties are bound to perform their contractual duties even if events have rendered performance more ones than could reasonably have been anticipated at the time of the conclusion of the Monthitstanding paragraph 1 of this Clause, where a Party proves that:

 (a) the continued performance of its contractual duties has become excessively onerous due to an event beyond its reasonable control which it could not reasonably have been expected to have taken into account at the time of the conclusion of the contract and that its corresponders, the Parties are (b) it could not reasonably here aexided or overcome the event or its engolistic elementate contractual terms which reasonably allow to overcome the consequences of the event.

 Where Clause 182 applies, but where the Parties have been unable to agree alternative contractual terms as provided in that paragraph, the Party mixed pits Clause is entitled to terminate the contract, but cannot request adaptation by the judge or arbitrator without the agreement of the other.

- invalidity, written form, place of jurisdiction and dispute resolution.

 All amendments and supplements must be in writing in order to be effective. This also applies to amendments and supplements to this clause 17.1. Should one or several of the provisions under the contract and/or less terms and conditions be Should one or several of the provisions under the contract and/or less terms and conditions to the state of the several orders of the several orders and the content of the results provision in legal and commercial terms.

 Unless otherwise stipulated in the contract, the governing law of the contract and these terms and conditions shall be chosen following the rules as below.

 Unless otherwise stipulated in the contract, the governing law of the contract and the settlems and conditions shall be chosen following the rules as below.

 It is not the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of the People's Republic of China.

 It TUV Rheeland in question is legally registered and existing in Taiwan, the contracting parties hereby agree that the contract and these terms and conditions shall be governed by the laws of the People's Republic of China. 19.2
- 19.3

- ITUV Rheritiand in question is legally registered and existing in 1-mm.

 The hereby agree that the contract and these terms and conditions shall be governed by the laws of Takwar.

 It TOV Rheritind in question is legally registered and existing in Hong Kong, the contracting is TOV Rheritind in the contract and these terms and conditions shall be governed by the laws of Hong Kong.

 Any dispute in connection with the contract and these terms and conditions or the execution thereof shall be settled friendly through negotiations.

 Unless otherwise seputated in the contract, if no cellement or no agreement in respect of the Unless otherwise seputated in the contract, and the contract and the settled friendly through negotiations.

 The contract is the contract of the cellement or no agreement in respect of the Unless otherwise seputated in the contract, if no settlement or no agreement in respect of the dispute, the dispute shall be submitted:

 The reached within the mornitin of the sitting of the dispute of the contract of the sitting of the dispute of China, to China International Economic and Trada Arbitration Commission (CETAC) submitted. The arbitration shall take place in Beijing, Shenghai, Shenchen or Chongqing as appropriately chosen by the claiming party, in the case of TUV Rheritand to fluestion being legally registered and existing in Takwan, to Chinaes Arbitration Association, Tages to be arbitrated in accordance with is then current Rules in the case of TUV Rheritand the langle goally registered and existing in Toky Rong, to Hong Kong, to Hong Kong to Ho









Test Report No.: TSNHL24001172801 Date: Jun 14, 2024 Page 1 of 6

Client Name: SHANDONG SHANGWEI MEDICAL PRODUCTS CO.,LTD

Client Address: NORTH ROAD, FUMIN AVENUE, QINGHE STREET, CAOXIAN, 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)

Jun 07, 2024 Sample Receiving Date:

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

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

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

Signed for and on behalf of SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.

Patrick Kou 寇怀江 Approved Signatory

This report is English version of TSNHL24001172802.



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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN. Doccheck-Ross.com

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

t (86-22) 65288000



Test Report No.: TSNHL24001172801 **Date:** Jun 14, 2024 Page 2 of 6

	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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Test Report No.: TSNHL24001172801 **Date:** Jun 14, 2024 Page 3 of 6

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:

 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

- $(3) \le less than$
- (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 Marinate						
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/dm²	3.0	ND	Pass

Notes:

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



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Test Report No.: TSNHL24001172801 **Date**: Jun 14, 2024 Page 4 of 6

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.

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

Test Item(s)	CAS No.	Limit	Unit(s)	RL	A1			
4% Acetic Acid(V/V)								
Migration times								
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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Test Report No.: TSNHL24001172801 **Date:** Jun 14, 2024 Page 5 of 6

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						

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 Page 6 of 6

Sample Photo:



SGS authenticate the photo on original report only

*** End of Report ***





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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:

Sample Information

Overall Rating:		
Data		
Satisfactory	~	
Unsatisfactory		
Others, See Detail Enclosed		

HQ2430601574

Client:	1		
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		

Page1of 3







Testing Report





Report No.: HQ2430601574-2

Testing Summary of Tested Component on Submitted Sample:

Microbiological **Pass**

HQTS QA International Services Co., Ltd.



Approved by

Noyel Luo

Issued Date: 2024-07-08







STING SERVI





Testing Report





Report No.: HQ2430601574-2

Microbiological

GB 15979-2002

Tested Component	Disposable Vinyl Glove			
Tested Item	Tested Method	Requirement (cfu/g)	Results (cfu/g)	Comment
	Hygienic standard for disposable			
Aerobic Bacterial	sanitary products	≤200	Not Detected	Pass
Count	for GB 15979-2002		Not Detected	F a 5 5
	The Microbiological tested annex B			
Molds and Yeast Count	Hygienic standard for disposable			
	sanitary products	≤100	Not Detected	Pass
	for GB 15979-2002		Not Detected	F a 5 5
	The Microbiological tested annex B			
	Hygienic standard for disposable			
Thermotolerant	sanitary products	Not Detected	Not Detected	Pass
Coliform Bacteria	for GB 15979-2002	Not Detected	Not Detected	rass
	The Microbiological tested annex B			4
	Hygienic standard for disposable			
Pseudomonas	sanitary products	Not Detected	Not Detected	Pass
Aeruginosa	for GB 15979-2002		Not Detected	rass į
	The Microbiological tested annex B			CE
Staphylococcus Aureus	Hygienic standard for disposable			ž <u>V</u>
	sanitary products	Not Detected	Not Detected	Pass
	for GB 15979-2002	Not Detected	Not Detected	rass
	The Microbiological tested annex B			
	Hygienic standard for disposable			
Hemolytic	sanitary products	Not Detected	Not Detected	Pass
streptococcus	for GB 15979-2002	NOI DEIECIEU	Not Detected	Газэ
	The Microbiological tested annex B			

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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

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

yh m

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





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

/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 Polyvinyl Chloride Examination Gloves, Disposable Polyvinyl Chloride and Nitrile Synthetic Examination Gloves,

Disposable Nitrile Examination Gloves

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

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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

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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