GUANTES EXAMEN VINILO
No Estériles, Sin Polvo

Presentación Caja de 100 Unidades Cartón 10 x 100	 
Dimensiones **CAJA 100 Uds.** Peso bruto: 490 g. Largo: 22,5 cm. Ancho: 11,5 cm. Alto: 5 cm. **CARTÓN 10 x 100 Uds.** Peso bruto: 5,1 Kg. Largo: 27 cm. Ancho: 24 cm. Alto: 23,5 cm	

Modelos / Referencias

Modelo	Referencia	EAN13
TALLA EXTRA PEQUEÑA	040099	8 435125 408837
TALLA PEQUEÑA	040100	8 435125 408097
TALLA MEDIANA	040101	8 435125 408103
TALLA GRANDE	040102	8 435125 408110
TALLA EXTRA GRANDE	040103	8 435125 415088

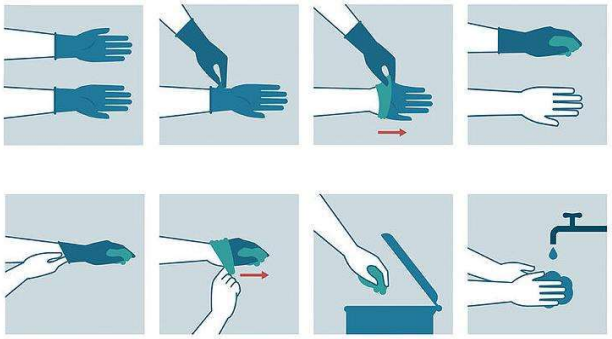
Características Técnicas

Guantes de examen, uso médico. Producto sanitario + Equipo de protección Individual (EPI)
Fabricado en vinilo (PVC).
Color blanco natural.
Desechables, un solo uso.
No estériles.
Sin polvo.
Libre de látex.
Sin lubricante.
Superficie texturizada, antideslizantes, resistentes y con sensibilidad al tacto.
Ambidextros, con reborde.
Dexteridad: 5
Propiedades químicas: Ph interior 7 ±1.

Características Técnicas	Libre de proteínas. Caducidad: 5 años desde fecha fabricación. Marca: Star Fabricante: Jiangxi Rainbow Medical Products Co., Ltd. Procedencia: China
Ingredientes Químicos Primarios	Polivinyl Chloride 45,80% Di-2-Ethylhexyl Phthalate 45,80% Di-2-Ethylhexyl Adipate 4,50% 2,2,4-Trimethly-1, 3-Pentanediol 2,30% Calcium, Zinc Sterates 0,50% Epoxidized Soybean Oil 0,90% Poly Urethane 0,20%

Regulación	Marcado "CE" Producto sanitario Clase I + Equipo de Protección Individual.
	EPI Categoría III, no estériles, según la directiva 2016/425. Declaración de conformidad del fabricante adjunta.
	Producto Sanitario Clase I No estéril según la directiva 2017/745. Declaración de conformidad del fabricante adjunta.
	Certificado CE Módulo B: adjunto
	Certificado CE Módulo C2: adjunto
	Cumplen con los requisitos según normas:
	- EN ISO 21420: 2020: Requisitos generales para guantes de protección.
	- EN ISO 374: Contra productos químicos y microorganismos peligrosos.
	  ○ EN 374-1: Índice de protección.
	  ○ EN 374-5: Terminología y requisitos de prestaciones para riesgos por microorganismos.
	- EN 455-1: 2000: Libre de agujeros
	- EN 455-2: 2015. Clausulas 4, 5 y 7: Tamaño, medida y etiquetado
	- EN 455-3: 2015. Clausula 7: Libre de agujeros
	Ver resultados en Test report adjunto

Uso	Especialmente indicado para prevención de contaminación entre personal sanitario y pacientes. Si se observaran reacciones alérgicas, suspender el uso, lavar las manos y solicitar ayuda médica si fuera necesario.
Conservación / Almacenaje	Mantener en lugar frío, seco y libre de polvo. Evitar humedad, luz solar directa y luz fluorescente. Mantener a temperatura no superior a 40º

Conservación / Almacenaje	Producto combustible, aunque no considerado muy peligroso Punto de fusión 195ºC Peligrosidad de los productos en la descomposición: Carbón monoxide, Carbón dioxide, ácido orgánico.
Instrucciones de uso	

DECLARATION of CONFORMITY
to Council Directive 93/42/EEC of 14 June 1993
concerning medical devices as amended by 2017/745

Manufacturer:	Jiangxi Rainbow Medical Products Co.,Ltd Add：East side of Jianshe Road, Penghuwan Industrail Park, Pengze 332700 Jiujiang CIty, Jiangxi Province
Medical Device:	Vinyl Examination Gloves
Classification:	Class I

We, Jiangxi Rainbow Medical Products Co.,Ltd. Herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by 2017/745; All supporting documentation is retained at the premises of the manufacturer.

EC REP
European Representative:

Place, Date of Declaration: China, Dec,12, 2020

Signature:

Managing Director

Jiangxi Rainbow Medical Products CO.,LTD
East side of Jianshe Road,Pengze,Jiujiang, Jiangxi, China,332700
Tel:+86-0512-81625989 Fax:+86-0512-58455833
www.rainbowmedica.com

DECLARATION OF CONFORMITY

Manufacturer's Name	: Jiangxi Rainbow Medical Products Co.,Ltd
Manufacturer's Address	: East side of Jianshe Road,Penghuwan Area Pengze,Jiujiang CIty,Jiangxi Province,China
European Authorized Representative	:
Product Type	: Disposable Vinyl Examination Gloves S/7-RBM-Vinyl M/8-RBM-Vinyl L/9-RBM-Vinyl XL/10-RBM-Vinyl
Standard	: EN ISO374-1:2016+A1:2018;EN ISO 374-5:2016; EN 1SO 21420:2020
Conformity Category	: III
Conformity Assessment Procedure	: Article 15 and Annex IX of Regulation(EU)2016/425
Conformity Route	: Certified by EU Notified Body: 2777

We herewith declare with our own responsibility that above mentioned product(s) with CE mark are fully compliance with Essential Requirement of the PPE Regulation (EU) 2016/425.

Certification Body :SATRA TECHNOLOGY

郑宇浩

Print Name: Zheng Yuhao

Issued to:

Jiangxi Rainbow Medical Products Co.,Ltd
East side of Jianshe Road
Penghuwan Industrial Area
Pengze
Jiujiang
Jiangxi
332700
China

Notified Body: 2777

SATRA customer number: P20173

EU Type-Examination Certificate

Certificate number: 2777/17971-02/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

RBM-VINYL-CLEAR
RBM-VINYL-BLACK
RBM-VINYL-BLUE
RBM-VINYL-CREAM

Description:

Disposable Vinyl Glove (Powder&Powder free)

Colour: Clear, Blue, Black, Cream

Sizes:
7(S)-10(XL)

Classification:

EN ISO 374-1:2016+A1:2018 /Type C	**Level**	**EN ISO 374-4:2019 Degradation %**
40% Sodium Hydroxide (K)	6	-1.6

EN ISO 374-5:2016	
Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0311666/2115, CHM0311124/2113/JH/A, CHM0311124/2113/JH/B

Signed on behalf of SATRA:

Quincey Brown

Date first issued: 13/08/2021
Date of issue: 18/08/2021
Expiry date: 13/08/2026

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.

PPE REGULATION (EU) 2016/425
MODULE C2 CERTIFICATE

Issued to:

Jiangxi Rainbow Medical Products Co.,Ltd
East side of Jianshe Road
Penghuwan Industrial Area
Pengze
Jiujiang
Jiangxi
China
332700

This is to certify that the following products tested under SATRA reports referenced: STE0302119 & CHM0302407/2038/LC have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/14972-01/E00-00	RMB-Vinyl	disposable vinyl gloves	EN ISO 3741:2016+A1:2018 Type C

Dated: 8th October 2020

This certificate is valid until: *October 2021*

Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited

CE

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.

SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P. Republic of Ireland.
(Notified Body number 2777)
Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 105935 0001 Rev. 00

Holder of Certificate: **Jiangxi Rainbow Medical Products Co., Ltd.**
East of Jianshe Road, Penghuwan Industrial Park, Pengze
332700 Jiujiang City, Jiangxi Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Jiangxi Rainbow Medical Products Co., Ltd.
East of Jianshe Road, Penghuwan Industrial Park, Pengze,
332700 Jiujiang City, Jiangxi Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Medical examination glove**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1943101

Valid from: 2020-03-02
Valid until: 2023-03-01

Date, 2020-03-02

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Test Report No. 7191212723-EEC19/01-WBH
dated 13 Aug 2019

PSB Singapore

Add value.
Inspire trust.

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Power-free Gloves submitted by Jiangxi Rainbow Medical Products Co.,Ltd. on 07 Jun 2019 and 29 Jul 2019.

TESTED FOR:

Jiangxi Rainbow Medical Products Co.,Ltd.
East Side of Jianshe Road, Penghuwan Industrial Area, Pengze,
Jiujiang City, Jiangxi Province, China

TEST DATE:

07 Jun 2019 to 24 Jun 2019 and 13 Aug 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Vinyl Gloves (Powder Free)	Clear	RB190518	M	400	Jiangxi Rainbow Medical Products Co., Ltd

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

1. EN 455-1:2000 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes

2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

Phone : +65-6885 1333
Fax : +65-6776 8670
E-mail: enquiries@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221

RESULTS:

Sample: Disposable Vinyl Gloves (Powder Free), Size M - Lot No.: RB190518

Table 1: Results for EN 455-1:2000

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	7	200	5	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	Median Length for size M: ≥ 240	13	245	Passed
	b) Width (mm)	Median Width for size M: 95 ± 10	13	95	Passed
5	Strength a) Force at break (N)	For examination gloves: ≥ 3.6	13	4.3	Passed
	b) Force at break after challenge testing (N) 7 days at (70 ± 2)°C	For examination gloves: ≥ 3.6	13	4.4	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Comply	Passed

Table 4: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.17 mg per glove	Passed

RESULTS (cont'd):

Sample: Disposable Vinyl Gloves (Powder Free), Size M - Lot No.: RB190518

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

REMARKS:

NA: Not applicable as the feature was not found on sample.

Lee Dai Yi
Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Disposable Vinyl Gloves (Powder Free), Size M - Lot No.: RB190518

PSB Singapore

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

SUBJECT	**Microbiological Analysis**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**JIANGXI RAINBOW MEDICAL PRODUCTS CO., LTD**
CLIENT ADDRESS	EAST SIDE OF JIANSHE ROAD, PENGHUWAN INDUSTRIAL AREA, PENGZE, JIUJIANG CITY, JIANGXI PROVINCE, CHINA
TEST PERIOD	17-Mar-2020~31-Mar-2020
TEST REQUEST	Penetration of Phi-X174 Bacteriophage Test - with reference to ASTM F 1671-2013

Prepared By	**Authorized By**
Judy hu	Liu
(Hu Ting)	(Liu Naikui)
Report Drafter	Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108 P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
Jiangsu TÜV Products Service Co.,Ltd. Shanghai Branch.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

RECEIPT DATE / TEST DATE

17-Mar-2020/ 17-Mar-2020

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: Vinyl Gloves
Sample Type: M
Batch No./Date: 2020.03.10
Manufactory: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721652740	Transparent gloves	

TEST METHOD(S)

Penetration of Phi-X174 Bacteriophage Test
- with reference to ASTM F 1671-2013 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

REQUIREMENT

- Exposure Procedure: B

Sampling Size: 75mm×75mm
Negative control: Polyethylene material
Positive control: 0.04 μm microporous membrane
Prior to testing, condition all test specimens and controls for a minimum of 24 hours at (21±5)℃ and 30%~80% relative humidity.

TEST ORGANISM(S)

Bacteriophage ATCC 13706-B1

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108 P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
Jiangsu TÜV Products Service Co.,Ltd. Shanghai Branch.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

PROCEDURE

1. Compatibility testing
   1.1. Test three specimens representing each material type to be tested.
   1.2. With the sterile cell placed horizontally on the laboratry bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
   1.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.
   1.4. With the cell remaining in the horizontal position on the laboratory bench, place a 2.0 µL aliquot of the Phi-X174 bacteriophage in bacteriophage nutrient broth, containing a total of 900-1200 PFU, near the middle of each piece of test specimen.
   1.5. Prepare a control by adding a 2.0 µL aliquot from the same suspension directly into 5.0 mL of sterile bacteriophage nutrient broth.
   1.6. After 60 min, quantitatively assay by adding 5.0mL of sterile bacteriophage nutrient broth onto the surface of the specimen.
   1.7. Calculate the ratio of the control assay titer to the test material assay titer using the following equation:

$$\text{ratio}=\frac{\text{control assay titer (PFU/mL)}}{\text{test material assay titer (PFU/mL)}}=1.2$$

   1.8. Record the initial titer of the Phi-X174 bacteriophage challenge suspension used for the test . ((2 ±1)x10^8 PFU/mL times the ratio calculated.)

2. Test procedure
   2.1. Prepare the bacteriophage challenge suspension (40-44 mN/m) for the test.
   2.2. With the sterile cell placed horizontally on the laboratry bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
   2.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.
   2.4. Mount the test cell in the test apparatus in a vertical position and close the drain valve.
   2.5. Penetration test: If liquid appears to penetrate through the test specimens at anytime during the test, terminate the test.
      (1) Carefully fill the test cell reservoir with approximately 60 mL of the Phi-XI74 bacteriophage challenge suspension
      (2) Step1: Observe for 5 min at 0 psi.
      Step2: Slowly increase the pressure to 2.0 psi at the rate of no more than 0.5 psi/s, keep the pressure at 2.0 psi, observe for 1 min.
      Step3: Slowly decrease the pressure to 0 psi at the rate of no more than 0.5 psi/s, observe for 54 min.
      (3) At the end of the time period, open the drain valve and drain the test cell of the bacteriophage challenge suspension. Dilute and assay the bacteriophage concentration.
   2.6. Specimen surface assay procedure
      (1) With the sterile cell placed horizontally on the laboratory bench. Slowly add 5.0 mL of sterile bacteriophage nutrient broth onto the exposed surface of the specimen.
      (2) Gently swirl the test cell for approximately 1 min. Assay the liquid soon after collecting.
   2.7. Remove the specimen from the test cell and prepare the test cell for sterilization.

3. Test controls
   3.1. The negative control was negative for bacteriophage penetration.
   3.2. The positive control was positive for bacteriophage penetration.
   3.3. Record the final titer of the bacteriophage challenge at the conclusion of the 60 min test.

TEST RESULT(S)

Test Items		Initial titer PFU/ml	Final titer PFU/ml	Test Results				
				Step1	Step2	Step3	Assay titer (PFU)	Pass /Fail
Penetration of Phi-X174 Bacteriophage	Control(+)	1.6×10^8	1.5×10^8	None Seen	Seen	-	-	Acceptable
	Control(-)	1.6×10^8	1.5×10^8	None Seen	None Seen	None Seen	<1	Acceptable
	-1	1.6×10^8	1.5×10^8	None Seen	None Seen	None Seen	<1	Pass
	-2	1.6×10^8	1.5×10^8	None Seen	None Seen	None Seen	<1	Pass
	-3	1.6×10^8	1.5×10^8	None Seen	None Seen	None Seen	<1	Pass

Note:
1.PFU: Plaque Forming Unit.
2.This report is for internal use only by the client
3. - Exposure Procedure: B
Retaining Screen:Stainless steel mesh screen
Diameter of the steel wire : 0.80mm
Retaining Screen pore: 2.0mm*2.0mm

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd
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Shanghai
201108 P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

Jiangxi Rainbow Medical Products CO.,LTD

Jishan Industrial Park,Pengze,Jiujiang City, Jiangxi, China,332700
Tel:+86-0512-81625988 Fax:+86-0512-58455833

Accelerated Aging Test Report

Product Name: Vinyl Glove(powder&powder free)

Lot#

Romm Temp./Relative Humidity: 25℃/53%

Sample Type: Clear powder free vinyl glove **Sample Size:** M

Testing Standard: EN455-4

Spec.	Before Accelerated Aging				After Accelerated Aging Aged Condition: 50℃×90Days									
	Test Date: 6/19/12				**Test Date:** 7/20/19,8/20/19,9/20/19									
Sample No.	**Weight(g)**	**Force at break (N)**	**Tensile Strength (Mpa)**	**Elongation (%)**	**Weight**	**Force at break (N)** 1m	2m	3m	**Tensile Strength (Mpa)** 1m	2m	3m	**Elongation (%)** 1m	2m	3m
1	4.3	3.62	9.20	350	4.3	3.62	3.61	3.61	9.20	9.05	9.00	350	345	345
2	4.4	3.74	9.15	361	4.4	3.73	3.70	3.70	9.15	9.10	9.10	360	355	355
3	4.5	3.67	8.96	388	4.5	3.67	3.67	3.67	8.95	8.95	8.90	385	380	380
4	4.5	3.52	9.50	322	4.5	3.51	3.48	3.47	9.50	9.50	9.50	322	318	315
5	4.4	3.46	9.66	305	4.4	3.44	3.45	3.44	9.66	9.60	9.60	305	300	300
6	4.5	3.63	10.15	362	4.5	3.63	3.60	3.60	10.1	10.0	10.0	360	355	358
7	4.3	3.62	9.84	351	4.3	3.62	3.62	3.61	9.80	9.75	9.75	350	345	346
8	4.4	3.45	9.31	342	4.4	3.44	3.45	3.45	9.30	9.30	9.30	340	336	330
9	4.5	3.50	9.66	340	4.5	3.50	3.50	3.48	9.60	9.60	9.60	340	340	340
10	4.3	3.53	10.20	350	4.3	3.50	3.51	3.50	10.20	10.10	10.00	350	346	345
11	4.5	3.58	10.67	351	4.5	3.58	3.55	3.55	10.60	10.60	10.60	350	350	350
12	4.4	3.62	9.75	360	4.4	3.62	3.61	3.60	9.75	9.70	9.70	358	355	355
13	4.5	3.76	9.38	359	4.5	3.77	3.75	3.75	9.35	9.30	9.30	355	355	350
14	4.4	3.68	10.16	355	4.4	3.68	3.66	3.66	10.10	10.00	9.98	350	350	350
15	4.4	3.66	10.33	349	4.4	3.65	3.66	3.64	10.30	10.20	10.20	349	350	345
16	4.5	3.67	9.48	352	4.5	3.66	3.65	3.65	9.48	9.45	9.46	350	349	349
17	4.5	3.59	9.87	357	4.5	3.58	3.55	3.55	9.88	9.84	9.82	355	355	355
18	4.4	3.65	9.12	360	4.4	3.65	3.60	3.60	9.10	9.05	9.08	360	356	355
19	4.5	3.67	9.22	371	4.5	3.67	3.65	3.65	9.20	9.20	9.20	370	369	369
20	4.3	3.74	10.51	364	4.3	3.74	3.72	3.73	10.50	10.50	10.40	360	360	360
21	4.5	3.72	9.49	336	4.5	3.70	3.70	3.69	9.45	9.44	9.45	335	335	330
22	4.4	3.69	9.34	351	4.4	3.69	3.66	3.66	9.30	9.30	9.27	350	350	350
23	4.5	3.65	10.10	367	4.5	3.62	3.65	3.62	10.00	9.99	9.98	366	366	360
24	4.5	3.74	9.99	375	4.5	3.72	3.73	3.70	9.99	9.98	9.99	375	374	374
25	4.3	3.59	9.36	366	4.3	3.58	3.58	3.58	9.35	9.33	9.30	366	362	362
26	4.4	3.62	9.33	361	4.4	3.60	3.61	3.61	9.30	9.30	9.30	360	360	360
27	4.4	3.60	9.45	358	4.4	3.60	3.60	3.60	9.40	9.45	9.40	358	355	355
28	4.5	3.57	9.21	364	4.5	3.55	3.55	3.54	9.20	9.23	9.18	360	360	359
29	4.3	3.62	9.60	379	4.3	3.60	3.61	3.60	9.55	9.55	9.52	378	375	375
30	4.5	3.66	11.13	355	4.5	3.66	3.62	3.58	11.10	11.00	11.00	355	350	350
Min	4.3	3.45	8.96	305	Min	3.44	3.45	3.44	8.95	8.95	8.90	305	300	300
Max	4.5	3.76	11.13	388	Max	3.77	3.75	3.75	11.10	11.00	11.00	385	380	380
Ave	4.425	3.63	9.73	354.8125	Ave	3.6184375	3.609375	3.6025	9.7003125	9.6659375	9.649375	353.5	351.125	350.21875

	VISUAL INSPECTION		**VISUAL INSPECTION**	1 M	2 M	3 M
	Critical	0/30	Critical	0/30	0/30	0/30
	Major	0/30	Major	0/30	0/30	0/30
	Minor	0/30	Minor	0/30	0/30	1/30
	Force at break(N):	3.63	**Force at break(N):**	3.61	3.61	3.60
	Tensile Strength(Mpa):	9.73	**Tensile Strength(Mpa):**	9.70	9.67	9.65
	Elongation at Break(%):	354.8	**Elongation at Break(%):**	353.5	351.1	350.2

Result: vinyl glove is valid for 5 years

Inspector:Wu Minzhong

Reviewed Date:9/20/19