



Packaging Dimensions (mm) & Loading Capabilities (Each product may differ from others)	L x W x H	Method 1 (1000 PCs/CTN)
	Dispenser	230x125x60mm
	Trans. CTN.	315x258x250mm
	Capability for 20 GP	1500 CTNs
	Capability for 40 GP	3100 CTNs
	Capability for 40 HQ	3450 CTNs

EU Type-Examination Certificate

Certificate number: 2777/14815-01/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:

Blue NGPF7000-7005
 Black BNPF7000-7005
 White WNPF7000-7005
 Violet NGPF7000-V1-7005-V1

Description:

Disposable Nitrile gloves(Non-sterile).

Sizes:

6-11(XS-XXL)

Classification:

EN ISO 374-1:2016+A1:2018/Type B

Sodium hydroxide 40%(K)
 Hydrogen peroxide 30%(P)
 Formaldehyde 37%(T)

Level

6
 2
 5

EN ISO 374-4:2019 Degradation %

-68.1
 30.5
 9.5

EN ISO 374-15:2016

Protection against bacteria and fungi
 Protection against viruses

Level

Pass
 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: CHT0296241/2012, CHM0298100/2020/EN/A, CHM0298100/2020/EN/B
 SGS: CH:TX:1142011147, CH:TX:1142011145-1, CH:TX:1142011148
 TUV: 7191234075-CHM20-02-TSL, 7191235025-EEC20-WBH_CR1. 721652920

Signed on behalf of SATRA:

Ting Huang

Ting Huang

Jacque Glasspool

Jacque Glasspool

Date first issued: 20/07/2020

Date of issue: 20/07/2020

Expiry date: 20/07/2025

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.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (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 manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
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 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 Regulation 2016/425.

TEST REPORT: 7191234075-CHM20-02-TSL

Date: 26 MAR 2020

Tel: +65 68851312 Fax: +65 67784301

Client's Ref:

Email: zhou.xiao@tuv-sud-psb.sg

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.



PSB Singapore

Add value.
Inspire trust.

SUBJECT

Determination of Glove Resistance to Permeation by 30% Hydrogen Peroxide

CLIENT

Anhui Intco Medical Products Co, Ltd
No.1 Haitang Road
Suixi District Economic Development Area
Huaibei City, Anhui Province
China

SAMPLE SUBMISSION DATE

13 Mar 2020

DESCRIPTION OF SAMPLE

One packet of glove sample labeled as follows was received.

No	Product Description	Colour	Sample Received (pieces)	Manufacturer
1	Disposable Nitrile Gloves (NBR)	Blue	20	Anhui Intco Medical Products Co, Ltd



DATE OF ANALYSIS

16 Mar 2020 – 25 Mar 2020



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

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Co. Reg : 199002667R

Regional Head Office:
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1 Science Park Drive, #02-01
Singapore 118221
TUV®

METHOD OF TEST

Determination of material resistance to permeation by chemicals : By EN 16523-1:2015

1. The palm area of the glove sample was mounted between two halves of a test cell. The test cell consisted of a two-compartment cell with 30% Hydrogen Peroxide on glove's normal outside surface and Ultrapure Water on the glove's normal inside surface. Testing were carried out at ambient temperature ($23^{\circ}\text{C} \pm 2^{\circ}\text{C}$).
2. The collecting medium were sampled and analysed for 30% Hydrogen Peroxide at 10 min (class 1), 30 min (class 2), 60 min (class 3), 120 min (class 4) , 240 min (class 5) and 480 min (class 6).
3. The extracts were then analysed by UV Spectrophotometer. The results were used to calculate the permeation rate of 30% Hydrogen Peroxide through the glove material. Based on the result, the minimum rate of sampling was determined.
4. The tests were repeated at 10 min, 30min and the sampling interval of 150 sec and collected until 60 mins.
5. The extracts were then analysed by UV Spectrophotometer for the Normalised Permeation Rate.
6. A blank test was carried out exactly with the same procedure except Ultrapure Water was used.

Table 1 : Classification of Glove Levels According to Breakthrough Time (EN 374-1 : 2003)

Breakthrough Time (mins) *	Types of Level
> 10	Class 1
> 30	Class 2
> 60	Class 3
> 120	Class 4
> 240	Class 5
> 480	Class 6

* The breakthrough time is deemed to have occurred when the analytical equipment detects a permeation rate of $1 \mu\text{g}/\text{cm}^2/\text{min}$.



RESULTS

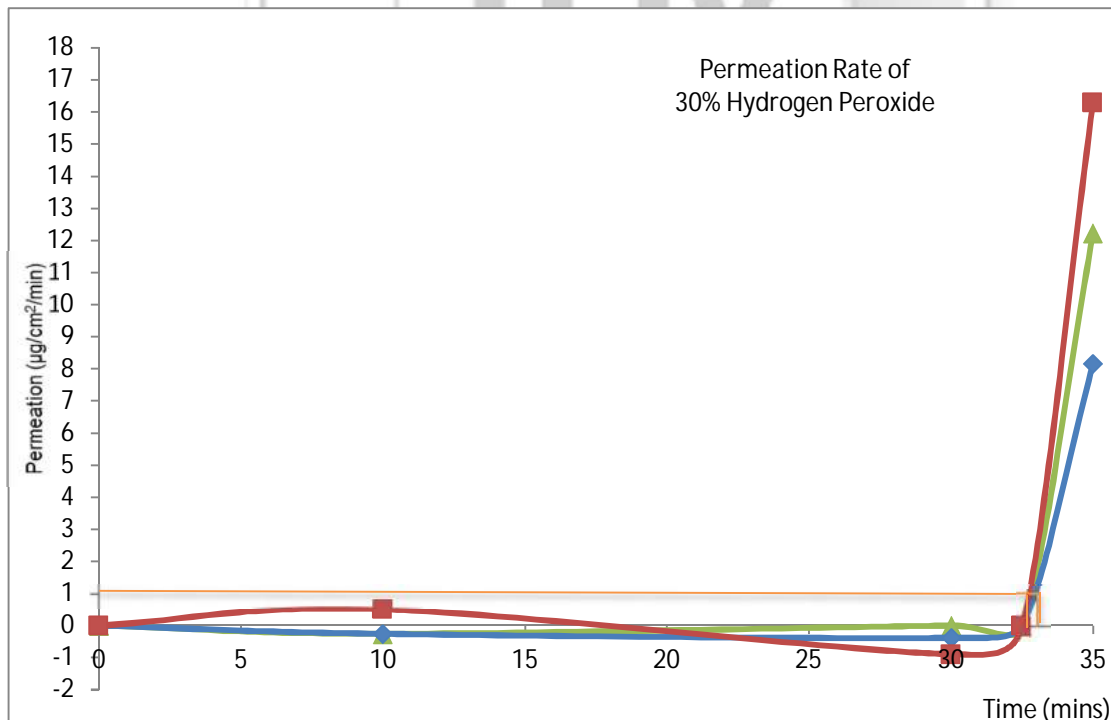
1. Determination of resistance to permeation by 30% Hydrogen Peroxide

Table 2 : Normalised Breakthrough Results for “Disposable Nitrile Gloves (NBR)” in 30% Hydrogen Peroxide

30% Hydrogen Peroxide					
Sample	Sample Location on Palm Area	Normalised Breakthrough Time (mins)	Mean Breakthrough Time (mins)	Lowest Value (mins)	Level
Disposable Nitrile Gloves (NBR)	1	34	34	34	2
	2	34			
	3	34			

- 1) Chemical transfer referred to the quantity of chemical which had passed through per cm² of glove sample at the termination of the test.
- 2) The thickness of the glove was 0.10 mm.
- 3) Slight color change was observed on the glove test specimen after the test.

According to Table 2, the breakthrough time for “Disposable Nitrile Gloves (NBR)” occurred after 30 mins. It was concluded that the sample belonged to class 2.



MS TAN SER LING
TECHNICAL EXECUTIVE

DR XIAO ZHOU
PRODUCT MANAGER
MICROCONTAMINATION DIAGNOSIS
CHEMICAL & MATERIALS

TEST REPORT: 7191234075-CHM20-02-TSL
26 MAR 2020



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



Customer details: SATRA Technology Services (Dongguan) Ltd SATRA reference: CHM0298100/2020/EN
Unit 110, Xinzhongyin Garden /A
Hongwei Road Your reference: CHT0297805
Xiping, Nancheng District
DONGGUAN CITY Date of report: 4th June 2020
Guangdong Province Samples received: 15th May 2020
China Date(s) work carried out: 20th to 26th May 2020
523079

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Anhui Intco Medical Products Co, Ltd
No 1 Haitang Road
Suixi District economic development area
Huaibei City
Anhui Province
China
235100

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Disposable Nitrile Glove.

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked \neq fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides a coverage probability of approximately 95%.

Report signed by: Emma Norris
Position: Technologist Team Leader
Department: Chemical & Analytical Technology

WORK REQUESTED:

Samples of gloves described as Disposable Nitrile Glove were received on the 15th May 2020 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

SAMPLES SUBMITTED:



Samples described as Disposable Nitrile Glove

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Disposable Nitrile Glove achieved the following performance levels:

Chemical	Performance level
37% Formaldehyde (CAS: 50-00-0)	5

Full results are reported in the following tables.

TESTING REQUIRED:

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

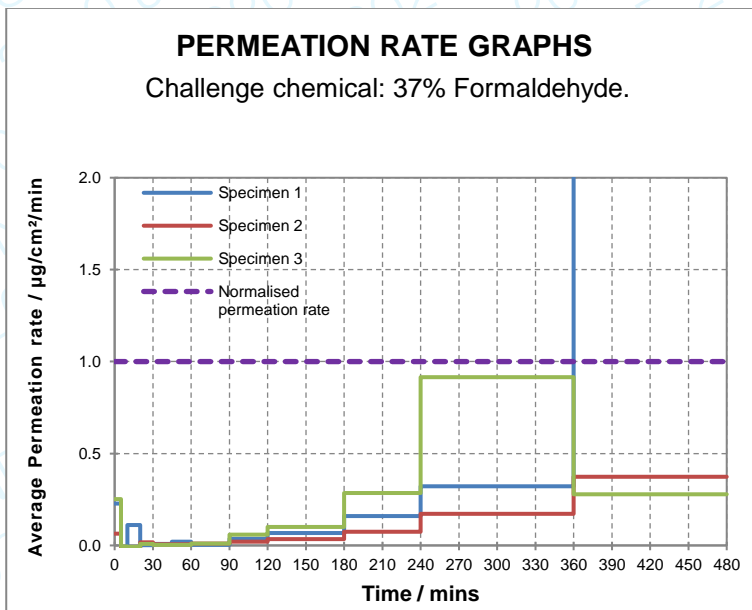
EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Performance levels are based on the lowest individual result achieved per chemical.

Test/Property	Sample reference:	Disposable Nitrile Glove		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 37% Formaldehyde		Level 5
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: HPLC-DAD (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)[△]	Breakthrough time (mins)[▽]	
	1	0.09	Between 361 to 480	
	2	0.10	>480	
	3	0.10	>480	
	Test result:	Between 361 to 480		
	UoM:	See below		
Visual appearance of specimens after testing:		Swollen and discoloured		

For SOP CAT-025, where both the P₁ and P_u are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.



Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

- △ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.
- ▼ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

 TECHNOLOGY

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- 1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing
- 1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to:
 - (a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
 - (b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
 - (c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).
- 1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.
- 1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

- 2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- 2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.
- 2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- 2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.
- 2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionsitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Client's failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and/or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
 - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
 - (b) fraud or fraudulent misrepresentation;
 - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
 - (d) defective products under the Consumer Protection Act 1987; or
 - (e) any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

- 6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- 6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- 6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
 - 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
 - 7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
 - 7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.
 - 7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

- 8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.
- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
- 10. PROVISION OF SERVICES**
- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.
- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.
- Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.
- Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.
- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.
- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.
- 11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES**
- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.
- 12. DELIVERY AND NON-DELIVERY OF GOODS**
- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- 12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).
- 13. RISK/TITLE OF GOODS**
- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -
- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- a) hold the Goods as SATRA's bailee;
- b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
- c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
- 14. PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.
- 15. WARRANTY OF GOODS**
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.
- 16. DEFECTIVE GOODS**
- 16.1 Subject to clauses 16.6 and 16.7 if:
- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
- b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

TEST REPORT

Report No. : CH:TX:1142011147

DATE : 19/03/2020



CASE NO: QDHL2002000969MD

ANHUI INTOCO MEDICAL PRODUCTS CO, LTD.
 NO.1, HAITANG ROAD, SUIXI DISTRICT ECONOMIC DEVELOPMENT AREA, HUAIBEI CITY,
 ANHUI PROVINCE.
A/C F619701 SGS-CSTC STANDARD TECHNICAL SERVICES (QINGDAO) CO., LTD.
CONTACT PERSON : --

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
 DISPOSABLE NITRILE GLOVE(NBR)
QD REF NO QDHL2002000969MD
PHOTO APPENDIX.



SAMPLE RECD ON 03/03/2020 **TESTING PERIOD :** 03/03/2020 - 19/03/2020

Summary of Test Results/Conclusion

Test Method / Standard	Clause/Test Name	Status / Performance Level
EN 16523-1:2015	Permeation by Liquid chemical under conditions of continuous contact.	
	Sodium hydroxide 40%	Level -6

Per pro SGS India Private Ltd.

K. PACHAIYAPPAN
ASST. MANAGER

Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

TEST REPORT

Report No. : CH:TX:1142011147

DATE : 19/03/2020



CASE NO: QDHL2002000969MD

RESULTS

EN 16523-1:2015 Determination of material resistance to permeation by chemicals – Part-1: Permeation by Liquid chemical under conditions of Continuous contact.

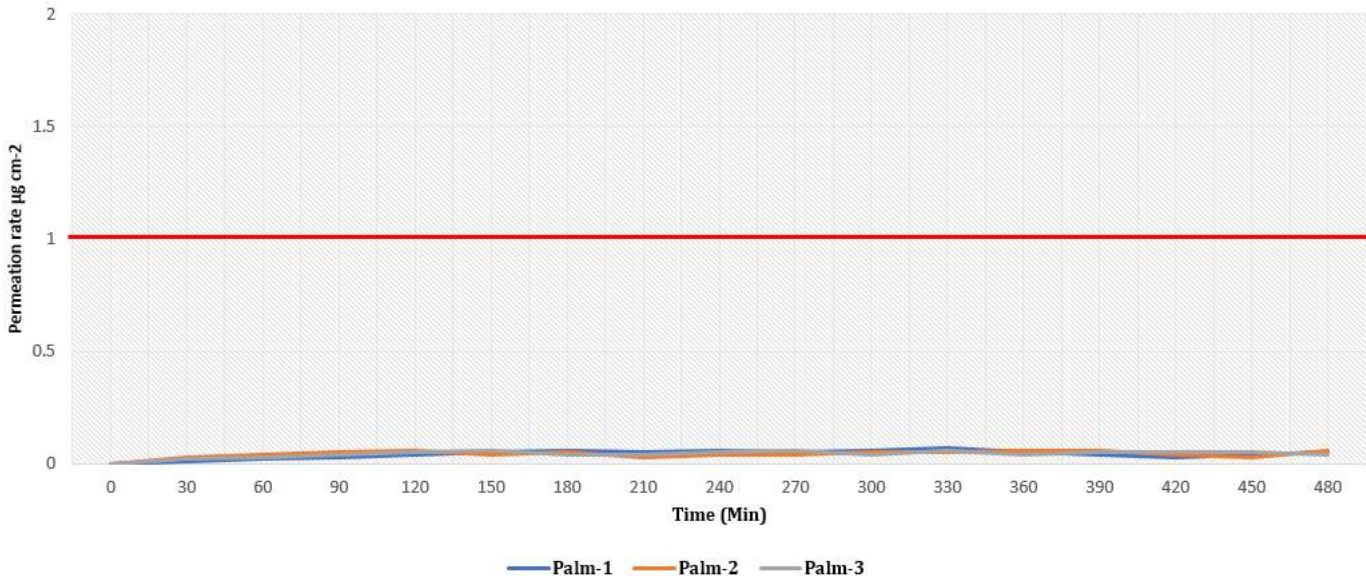
Chemical CAS NO	Loop system/collection medium	Analytical technique used	Mean thickness (mm)	NBT at NPR $1.0 \mu\text{g cm}^{-2} \text{min}^{-1}$ (minutes)	Performance level accordance to EN ISO 374-1: 2016 Table 1	Observation
Sodium hydroxide 40% 1310-73-2	Closed loop/ Grade 3 water	Continuous measurement With Conductivity electrode	0.08 0.08 0.09	> 480 > 480 > 480	Level - 6	No change

EN ISO 374-1:2016 – Protective gloves against dangerous chemicals and micro-organisms.
Part 1: Terminology and performance requirements for chemical risks.
Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Performance levels are based on the lowest individual results achieved per chemical

Sodium Hydroxide 40% Permeation Graph



***** End of Report*****

JOE No. : 2042806054

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Control No.:1142513791

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CNAS L0604

Test Report

No.: QDHL2004003646MD

Date: MAY.18,2020

Page: 1 of 2

ANHUI INTCO MEDICAL PRODUCTS CO,LTD
NO.1 HAITANG ROAD,SUIXI DISTRICT ECONOMIC
DEVELOPMENT AREA,HUAIBEI CITY,ANHUI PROVINCE.

The following sample(s) was/were submitted and identified by the client as:

Sample Description : DISPOSABLE NITRILE GLOVE(NBR)
Lot No. : NOT PROVIDED
Lot Size : NOT PROVIDED
Sample Quantity : 220PCS
Sample Receiving Date : APR.29,2020
Testing Period : APR.29,2020 TO MAY.18,2020
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested : BS EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE –
PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM
HOLES (CLAUSE 5.1)
Test Result(s) : PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion : THE SUBMITTED SAMPLE MET THE REQUESTED TEST
REQUIREMENT.

Remark: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

Jessica Gao

scan to see the report



QDHL2004003646MD

Jessica Gao
Approved Signatory



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Test Report

No.: QDHL2004003646MD

Date: MAY.18,2020

Page: 2 of 2

Test Conducted:

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

Number of test sample	:	200 Pieces
Number of non-conforming gloves	:	0

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note : 1 Sample quantity: 200pcs, AQL:1.5, Ac:10, Re:11, Found:0.
The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:

Received sample



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End of Report



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Test Report

No.: QDHL2004003645MD

Date: MAY.18,2020

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Client name : ANHUI INTOCO MEDICAL PRODUCTS CO., LTD
 Client address : NO.1 HAITANG ROAD, SUIXI DISTRICT ECONOMIC DEVELOPMENT AREA, HUAIBEI CITY, ANHUI PROVINCE.
 Sample Description : DISPOSABLE NITRILE GLOVE (NBR)
 Lot No. : NOT PROVIDED
 Lot Size : NOT PROVIDED
 Sample Quantity : 30PCS

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

Sample Receiving Date : APR.29,2020
 Test Performing Date : APR.29,2020 TO MAY.18,2020
 Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
 Test Requested : BS EN 455-2:2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES (CLAUSE 4.2, 4.3, 5.2, 5.3)
 Test Result(s) : PLEASE REFER TO THE FOLLOWING PAGE(S)
 Conclusion : THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

Remark: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

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 Co., Ltd.

Jessica Gao



Jessica Gao
 Approved Signatory

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Test Report

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Date: MAY.18,2020

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Test Conducted:

BS EN 455-2:2015 Medical gloves for single use – part 2: Requirements and testing for physical properties

Number of test sample	:	26 Pieces
Type	:	Examination/procedure gloves b)
Size	:	Examination/procedure gloves: M

Clause	Test Items	Result
4	Dimensions	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)

Test Result:

Result 1: Dimensions

No.	Size: M	
	Length (mm)	Width (mm)
1	247	99
2	240	98
3	240	100
4	240	100
5	244	99
6	244	99
7	242	99
8	241	99
9	243	99
10	243	99
11	246	99
12	241	100
13	241	99
Standard requirement	≥240	95±10
Median value	242	99

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Test Report

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Result 2: Strength

Size: M			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	7.1	1	7.1
2	6.4	2	7.9
3	7.7	3	6.7
4	7.1	4	6.8
5	8.2	5	6.8
6	8.2	6	7.3
7	7.7	7	6.3
8	6.4	8	6.4
9	6.2	9	6.8
10	6.7	10	7.2
11	7.9	11	6.7
12	6.0	12	7.3
13	6.6	13	6.7
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	7.1	Median value	6.8

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

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Test Report

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Sample Photo:

Received sample



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Test Report

No.: QDHL2004003647MD

Date: MAY.08,2020

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ANHUI INTOCO MEDICAL PRODUCTS CO, LTD
NO.1 HAITANG ROAD, SUIXI DISTRICT ECONOMIC
DEVELOPMENT AREA, HUAIBEI CITY, ANHUI PROVINCE.

The following sample(s) was/were submitted and identified by the client as:

Sample Description : DISPOSABLE NITRILE GLOVE (NBR)
Lot No. : NOT PROVIDED
Lot Size : NOT PROVIDED
Sample Quantity : 15PCS
Sample Receiving Date : APR.29,2020
Testing Period : APR.29,2020 TO MAY.08,2020
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested : BS EN 455-3:2015 MEDICAL GLOVES FOR SINGLE USE—PART 3:
REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION
(CLAUSE 4.4)
Test Result(s) : PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion : THE SUBMITTED SAMPLE MET THE REQUESTED TEST REQUIREMENT.

Remark: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

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Co., Ltd.

Jessica Gao



Jessica Gao
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Test Report

No.: QDHL2004003647MD

Date: MAY.08,2020

Page: 2 of 2

Test Conducted:

BS EN 455-3:2015 Medical gloves for single use—Part 3:Requirements and testing for biological evaluation

Number of test sample	:	5 Pieces
Finishes of gloves	:	Powdered – free gloves other than surgeon's gloves

Clause	Test Items	Result	Note
4.4	Powder-free gloves	Pass	# 1

Notes : #1 Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.16mg. (Requirement: For powder-free gloves the total quantity of powder residues shall not exceed 2 mg per glove.)

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:



SGS authenticate the photo on original report only

End of Report



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QD 7357394



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 Anhui Intco Medical Products Co., Ltd

CLIENT ADDRESS No.1 Haitang Road, Suixi District economic development area, Huaibei City, Anhui Province.

TEST PERIOD 24-Mar-2020~20-Apr-2020

TEST REQUEST Penetration of Phi-X174 Bacteriophage Test - with reference to ISO 16604-2004, BS EN ISO 374-5:2016

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By



Leo Liu
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.

RECEIPT DATE / TEST DATE

24-Mar-2020/ 24-Mar-2020

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

BY/ ON BEHALF OF THE CLIENTS AS:

Sample Name: Disposable Nitrile Gloves (NBR)

Sample Specification: /

Batch No./Date: /

Manufacturer: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721652920	Blue Gloves	

TEST METHOD(S)

Penetration of Phi-X174 Bacteriophage Test

- in accordance with BS EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms Part 5: Terminology and performance requirements for micro-organisms risks, 5.3 Protection against viruses. Test method with reference to ISO 16604-2004 Clothing for protection against contact with blood and body fluids -Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage

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)°C and 30%~80% relative humidity.

TEST ORGANISM(S)

Bacteriophage ATCC 13706-B1

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 laboratory 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 5.0 mL 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:
$$\text{ratio} = \frac{\text{control assay titer (PFU/mL)}}{\text{test material assay titer (PFU/mL)}} = 1.1$$
- 1.8. Record the initial titer of the Phi-X174 bacteriophage challenge suspension used for the test. ($(2 \pm 1) \times 10^8$ 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 laboratory 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-X174 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				Pass/Fail
				Step1	Step2	Step3	Assay titer (PFU/ml)	
Penetration of Phi-X174 Bacteriophage	Control(+)	1.9x10 ⁸	1.8x10 ⁸	None Seen	Seen	-	-	Acceptable
	Control(-)	1.9x10 ⁸	1.8x10 ⁸	None Seen	None Seen	None Seen	<1	Acceptable
	-1	1.9x10 ⁸	1.8x10 ⁸	None Seen	None Seen	None Seen	<1	Pass
	-2	1.9x10 ⁸	1.8x10 ⁸	None Seen	None Seen	None Seen	<1	Pass
	-3	1.9x10 ⁸	1.8x10 ⁸	None Seen	None Seen	None Seen	<1	Pass

Note:

- 1.PFU: Plaque Forming Unit.
- 2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

