
INTCO
SYNGUARD
NITRILE
EXAM GLOVES
POWDER-FREE
XS
6
100
GLOVES
AQL
1.5
EN
455
MD
CE 2777
REF SNBE10013

INTCO
英科环保

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1. Product Flat-Outs

INTCO

XS	SNBE10013	Extra-Small, Extra-klein, Très Petit(TP), Extra pequeño, Extra-pequeno, Extra Piccolo
S	SNBE10014	Small, Klein, Petit(P), Pequeño, Pequeno, Piccolo
M	SNBE10015	Medium, Mittel, Moyen(M), Mediano, Médio, Medio
L	SNBE10016	Large, Groß, Grand(G), Grande, Grande, Grande
XL	SNBE10017	Extra-Large, Extra-groß, Très Grand(TG), Extra grande, Extra grande, Extra Grande

EN Disposable examination and protective gloves made of nitrile; powder-free; non-sterile.
Warning: Contact with food (except acidic food) is allowed. Latex-free, powder-free, and DEHP/DOP-free. Compliant with MD Regulation (EU)2017/745(Class I), EN455-1:2000, EN455-2:2015, EN455-3:2015, EN455-4:2009, PPE Regulation (EU)2016/425(CAT III), EN ISO 21420:2020, and EN ISO 374. Check for the damage before use. Do not use damaged gloves. Visit the following link to read more about and download the Declaration of Conformity:
http://www.intcomedical.com/download.html
Donning & doffing gloves in a proper way is a skill that needs to be practised by healthcare workers and others that use gloves. Donning must be performed in the correct order to prevent transmission of infections. Keep hands clean before donning gloves. When removing the gloves, avoid allowing the outer surface of the gloves to come in contact with your skin, because the surface may have been contaminated with blood and other body fluids. Avoid snapping, as this may cause contaminants to splash into your eyes or mouth or onto your skin or other people nearby.

DE Einweg-Untersuchungs- und Schutzhandschuhe aus Nitril; puderfrei; nicht steril.
Warnung: Kontakt mit Lebensmitteln (außer mit säurehaltigen Lebensmitteln) ist erlaubt. Latexfrei, puderfrei und DEHP/DOP-frei. Konform mit MD-Verordnung (EU) 2017/745(Class I), EN455-1:2000, EN455-2:2015, EN455-3:2015, EN455-4:2009, PSA-Verordnung (EU) 2016/425(CAT III), EN ISO 21420:2020 und EN ISO 374. Prüfen Sie vor der Verwendung auf Beschädigungen. Verwenden Sie keine beschädigten Handschuhe. Besuchen Sie den folgenden Link, um mehr über die Konformitäts-erklärung zu erfahren und diese herunterzuladen:
http://www.intcomedical.com/download.html
Das richtige An- und Ausziehen von Handschuhen ist eine Fähigkeit, die von Mitarbeitern des Gesundheitswesens und anderen, die Handschuhe verwenden, geübt werden muss. Das Anziehen muss einem bestimmten Ablauf folgen, um die Übertragung von Infektionen zu verhindern. Halten Sie Ihre Hände sauber, bevor Sie Handschuhe anziehen. Vermeiden Sie beim Ausziehen der Handschuhe, dass die Außenfläche der Handschuhe mit Ihrer Haut in Kontakt kommt, da die Oberfläche mit Blut und anderen Körperflüssigkeiten kontaminiert sein könnte. Vermeiden Sie das Anspannen der Handschuhe, da dadurch Verunreinigungen in Ihre Augen oder Ihren Mund oder auf Ihre Haut oder andere Personen in der Nähe spritzen können.

ES Guantes de protección y examen desechables de nitrilo, sin polvo, no estériles.
Advertencia: Pueden entrar en contacto con alimentos (excepto con alimentos ácidos). Sin látex, sin polvo y sin DEHP/DOP. Conformes con el Reglamento (UE) 2017/745(Class I) sobre productos sanitarios, la norma EN455-1:2000, EN455-2:2015, EN455-3:2015, EN455-4:2009, el Reglamento (UE) 2016/425(CAT III) sobre equipos de protección individual y las normas EN ISO 21420:2020 y EN ISO 374. Compruebe que no estén dañados antes de su uso. No utilice guantes que estén dañados. Visite el siguiente enlace para más información al respecto y para descargar la Declaración de Conformidad:
http://www.intcomedical.com/download.html
Ponerse y quitarse los guantes de forma adecuada es una habilidad que el personal sanitario y otras personas que utilicen guantes deben practicar. La colocación debe realizarse en el orden correcto para evitar la transmisión de infecciones. Asegúrese de tener las manos limpias antes de ponerse los guantes. Al quitarse los guantes, evite que la superficie exterior de los guantes entre en contacto con su piel, ya que la superficie puede haberse contaminado con sangre y otros fluidos corporales. Evite romperlos, ya que esto podría ocasionar que los contaminantes le salpiquen a los ojos, a la boca, a la piel o a otras personas cercanas.

FR Gants d'examen et de production jetables en nitrile ; non poudrés ; non stériles.
Avertissement : le contact avec les denrées alimentaires (sauf les aliments acides) est autorisé. Sans latex, non poudrés, sans DEHP/DOP. Conformes au règlement relatif aux dispositifs médicaux (UE) 2017/745(Class I), à la norme EN455-1:2000, EN455-2:2015, EN455-3:2015, EN455-4:2009, au règlement relatif aux équipements de protection individuelle (UE) 2016/425(CAT III) et aux normes EN ISO 21420:2020 et ISO 374. Vérifiez l'absence de détérioration avant utilisation. N'utilisez pas de gants endommagés. Pour en savoir plus et télécharger le certificat de conformité, visitez le lien suivant :
http://www.intcomedical.com/download.html
La manière d'enfiler et d'enlever les gants correctement est une technique à laquelle doivent s'exercer les personnels de santé, ainsi que les autres personnes qui utilisent des gants. L'enfilage doit être effectué dans l'ordre correct afin d'éviter la transmission d'infections. Ayez les mains propres avant d'enfiler les gants. Lorsque vous retirez les gants, évitez de mettre leur surface extérieure en contact avec la peau, car cette surface peut avoir été contaminée par du sang et d'autres fluides corporels. Évitez de les distendre, car le retour brusque à leur forme initiale risquerait de projeter des contaminants dans les yeux ou la bouche, sur votre peau ou sur d'autres personnes à proximité.

IT Guanti monouso da esplorazione e protettivi realizzati in nitrile, privi di polvere, non sterili.
Avvertenza: Il contatto con alimenti è consentito (eccetto alimenti acidi). Privi di lattice, polvere e DEHP/DOP. Conformi a Regolamento sui dispositivi medicali (UE) 2017/745(Class I), EN455-1:2000, EN455-2:2015, EN455-3:2015, EN455-4:2009, Regolamento sui dispositivi di protezione individuale (UE) 2016/425(CAT III), EN ISO 21420:2020 ed EN ISO 374. Controllare che non presentino danni prima dell'uso. Non utilizzare guanti danneggiati. Visitare il seguente link per leggere altre informazioni e scaricare la Dichiarazione di conformità:
http://www.intcomedical.com/download.html
Indossare e rimuovere i guanti in modo corretto rappresenta un'abilità che deve essere praticata da operatori sanitari e altri soggetti che utilizzano i guanti. Indossare nell'ordine corretto, al fine di evitare la trasmissione di infezioni. Prima di indossare i guanti le mani devono essere pulite. Quando si rimuovono i guanti, evitare di far entrare in contatto la superficie esterna dei guanti con la pelle, poiché la superficie potrebbe essere contaminata da sangue o altri liquidi corporei. Evitare la rottura in quanto potrebbe comportare schizzi di contaminanti negli occhi, nella bocca, sulla pelle o su altri soggetti che si trovano nelle vicinanze.

PT Luvas de examinação e proteção descartáveis feitas de nitrilo; sem pó; não esterilizadas.
Aviso: O contacto com alimentos (exceto alimentos ácidos) é permitido. Sem látex, sem pó e sem DEHP/DOP. Em conformidade com o Regulamento (UE) 2017/745(Class I) relativo a dispositivos médicos, EN455-1:2000, EN455-2:2015, EN455-3:2015, EN455-4:2009, Regulamento (UE) 2016/425(CAT III) relativo aos equipamentos de proteção individual, EN ISO 21420:2020 e EN ISO 374. Verifique a eventual existência de danos antes de utilizar. Não utilize luvas danificadas. Visite a ligação seguinte para saber mais sobre e descarregar a Declaração de Conformidade:
http://www.intcomedical.com/download.html
Calçar e remover as luvas de forma adequada é uma habilidade que tem de ser praticada pelos profissionais de saúde e outras pessoas que utilizem luvas. Deverá calçar as luvas de forma correta para evitar a transmissão de infeções. Limpe as mãos antes de calçar as luvas. Ao remover as luvas, evite que a superfície externa das luvas entre em contacto com a sua pele, porque a superfície pode ter sido contaminada com sangue ou outros fluidos corporais. Evite puxões, uma vez que estes poderão fazer com que os contaminantes sejam salpicados para os seus olhos ou boca ou para a sua pele e das pessoas que se encontrem à sua volta.

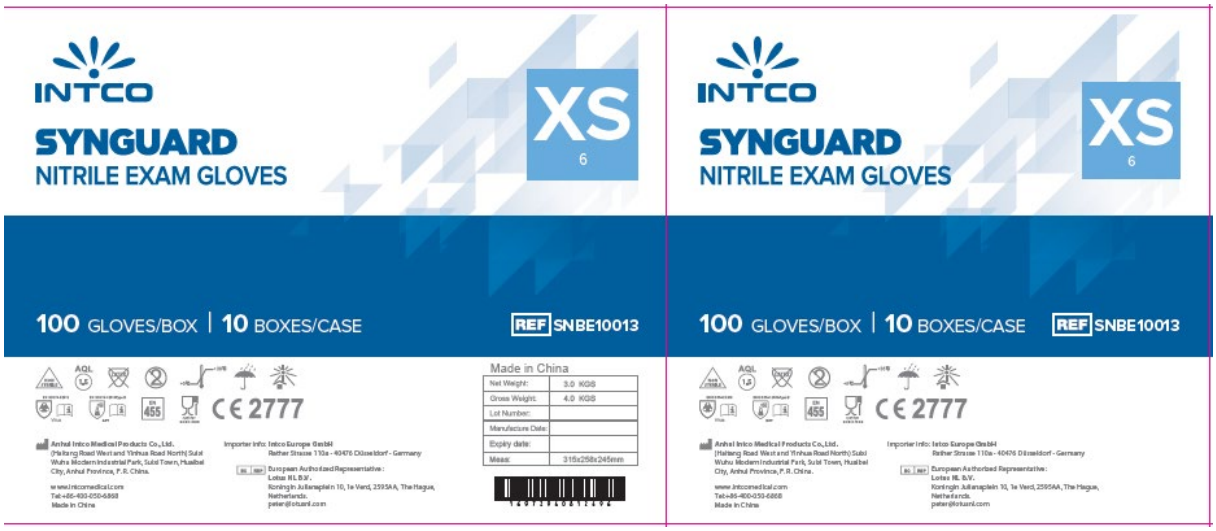
Anhui Intco Medical Products Co.,Ltd.
(Haitang Road West and Yinhua Road North) Suixi Wuhu Modern Industrial Park, Suixi Town, Huaibei City, Anhui Province, P. R. China.
www.intcomedical.com
Tel:+86-400-050-6868
Made in China

Importer info:
Intco Europe GmbH
Rather Strasse 110a - 40476 Düsseldorf - Germany

EC REP
European Authorized Representative:
Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
peter@lotusnl.com

LOT

6 972940 812699


INTCO
SYNGUARD
NITRILE EXAM GLOVES
XS
6
100 GLOVES/BOX | 10 BOXES/CASE
REF SNBE10013
CE 2777
Made in China
Net Weight: 3.0 KGS
Gross Weight: 4.0 KGS
Lot Number:
Manufacture Date:
Expiry date:
Meas: 315x258x245mm
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SYNGUARD
NITRILE EXAM GLOVES
XS
6
100 GLOVES/BOX | 10 BOXES/CASE
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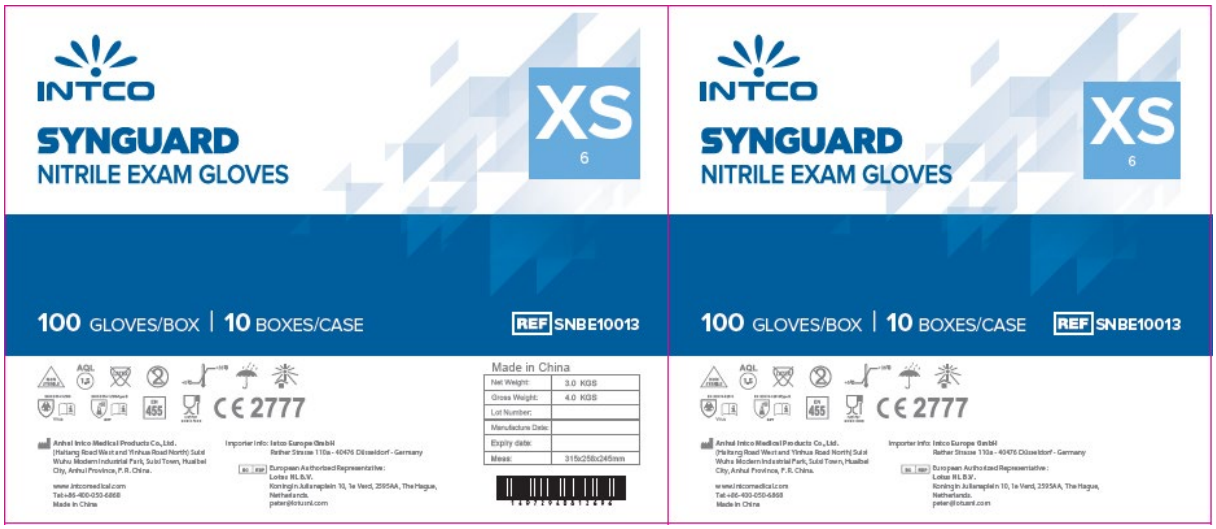
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2. Declaration of Conformity & PPE Certificates

INTCO
英科医疗

Document Number ：INTCO-CE-DC-NBR-001 Version: A/4

EU DECLARATION OF CONFORMITY

Manufacturer	Authorized Representative
Name: **Shandong Intco Medical Products Co., Ltd.**	*Name:* **Lotus NL B.V.**
Address: **Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China**	*Address:* **Koningin Julianaplein 10, le Verd, 2595AA， The Hague，Netherlands**

Declares that the MDR described hereafter

Product name and model:

Disposable Nitrile（NBR）Gloves

UMDNS code：11882

Model: XS /S /M /L /XL/XXL

UDI-DI:

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them.

The medical device has been assigned to Class I, based on rule 1 of Annex VIII Chapter III of the Regulation EU 2017/745 MDR. It bears the mark

CE

This Declaration of conformity is valid for five years: 7 / May / 2020 to 6 / May / 2025. If there is a change in the declaration information, this declaration is invalid.

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: Shandong Intco Medical Products Co., Ltd.
Address: Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China.

Shandong 2020-05-07 — *Place , date*

Cui Zhongqiang, Quality Manager — *Legally binding signature, Function*

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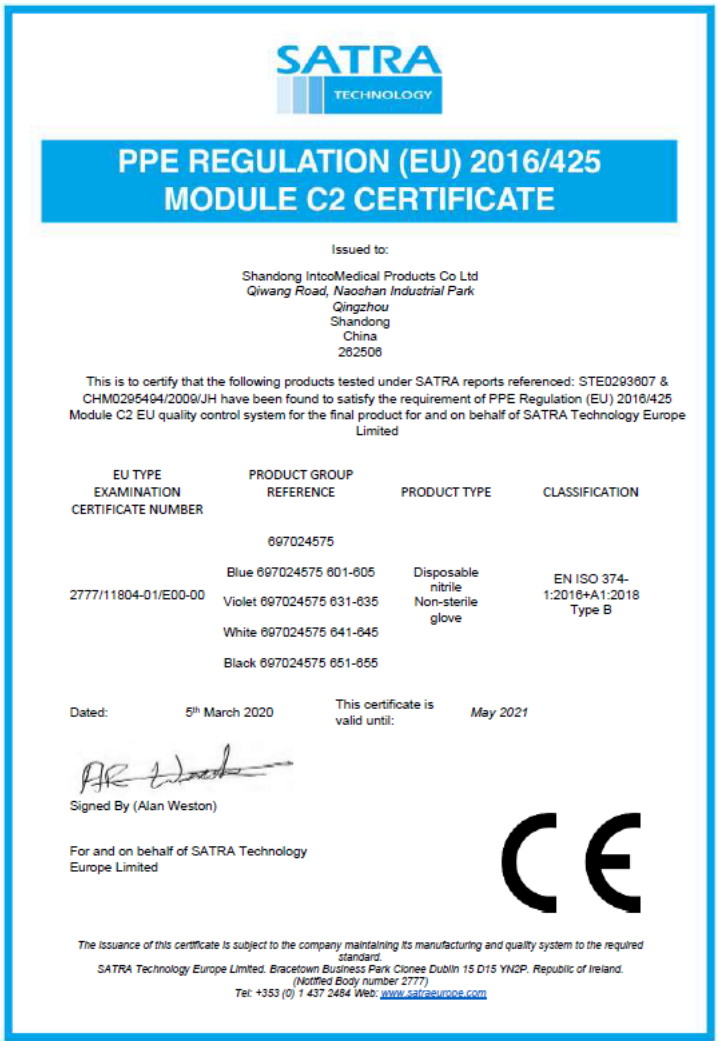

SATRA TECHNOLOGY

PPE REGULATION (EU) 2016/425 MODULE C2 CERTIFICATE

Issued to:

Shandong IntcoMedical Products Co Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou
Shandong
China
262506

This is to certify that the following products tested under SATRA reports referenced: STE0293607 & CHM0295494/2009/JH 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
2777/11804-01/E00-00	697024575 Blue 697024575 601-605 Violet 697024575 631-635 White 697024575 641-645 Black 697024575 651-655	Disposable nitrile Non-sterile glove	EN ISO 374-1:2016+A1:2018 Type B

Dated: 5th March 2020 This certificate is valid until: *May 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

3. EN374-1

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SGS

TEST REPORT

Report No. : CH:TX:6420076491 **DATE : 24/12/2015**

QDHG1511005851CO

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD.
QIWANG ROAD, NAOSHAN INDUSTRIAL PARK. QINGZHOU,
SHANDONG,
P.R.CHINA
A/C SGS-CSTC HARDGOODS SERVICES.,
CONTACT PERSON : --

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

PHOTO APPENDIX

SAMPLE RECD ON 22/12/2015 **TESTING PERIOD :** 22/12/2015 - 24/12/2015

Summary of Test Results		
Test Method	**Test Name**	**Status / Performance Level**
EN 374-1:2003	**Minimum Liquid Proof Length**	
	Size XS,S,M,L,XL	Pass

Per pro SGS India Private Ltd.

K. Pachaiyappan

K. PACHAIYAPPAN
SECTION INCHARGE
Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

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SGS

TEST REPORT

Report No. : CH:TX:6420076491 **DATE : 24/12/2015**

QDHG1511005851CO

RESULTS

EN 374-1 : 2003 Protective Gloves against Chemicals and Micro Organisms – Minimum Liquid Proof Length

Clause	Test Name	Result		Average	Requirements as per EN 420: 2003 (5.1.2)	Status
5.1	Minimum Length of Glove					
	Declared Size XS	242	235	238.5	Min : 220 mm	Pass
	Declared Size S	242	241	241.5	Min : 230 mm	Pass
	Declared Size M	240	240	240.0	Min : 240 mm	Pass
	Declared Size L	253	255	254.0	Min : 250 mm	Pass
	Declared Size XL	260	261	260.5	Min : 260 mm	Pass

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

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4. EN374-2

SHANGHAI
3F, Building Block 2, No. 3400 Gonghexin Road,
Jing'an District - Shanghai 200436, P.R. CHINA
上海市静安区共和新路3400号2幢3层
Tél. : +86 21 68 55 50 32
Fax : +86 21 68 55 50 33
E-mail : ctcshanghai@ctcgroupe.com

TEST REPORT

Report No.: S200908976_2 15 September 2020

APPLICANT: SHANDONG INTCO MEDICAL PRODUCTS CO. LTD (C41221)

huangcongmin@intco.com

NO. 9888 QIWANG ROAD, NAOSHAN
INDUSTRY PARK
QINGZHOU SHANDONG
CHINA

Date of receipt :04 Sept. 2020
Testing period :07 Sept. 2020
:08 Sept. 2020

Buyer: --

Sample description: Disposable Nitrile gloves (NBR), 6XS, 7S, 8M, 9L, 10XL, 11XXL

Test(s) requested :--
Service :REGULAR
Brand / Section :--
Season :--
End use :--
Factory name :--
Factory code :--
Revision :Amend sample information

For CE Marking : Yes
Previous report :--
Product category :--
Product type :--
Test stage :FIRST TEST
Supplier name :--
Exported to :--

1. Conclusion:

	Tests description	Conformity
	EN ISO 374-1	
1	Air Leak Test	Pass
2	Water Leak Test	Pass

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable

Approved by

Henry YAN
Laboratory Manager

CTC SHANGHAI

TEST REPORT

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Report No.: S200908976_2 15 September 2020

APPLICANT: SHANDONG INTCO MEDICAL PRODUCTS CO. LTD (C41221)

2. Sample(s) description assigned by laboratory:

Size	Analyzed product	Description	Sample information
	GLOVE	Whole glove	

200908976

CTC SHANGHAI

TEST REPORT

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Report No.: S200908976_2 15 September 2020

APPLICANT: SHANDONG INTCO MEDICAL PRODUCTS CO. LTD (C41221)

3. GLOVE/

Whole glove

	Method	Client Requirement	Unit	Result	Conformity
• 5.2. **Air Leak Test**	EN 374-2:2019				Pass
Glove thickness			mm	0.10	
Air pressure used to test			kPa	3.0	
Result		No air bubbles		No air bubbles	
• 5.2. **Water Leak Test**	EN 374-2:2019				Pass
Result		No water leak		No water leak	

END OF TEST REPORT

•: The test was carried out by external accredited laboratory, not within their accreditation scope.

5. EN374-4

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SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.com
www.satra.com

0248

Customer details: SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden
Hongwei Road
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0303384/2041/JH
Your reference: CHT0303055
Date of report: 30th October 2020
Samples received: 6th October 2020
Date(s) work carried out: 16th to 20th October 2020

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: SHANDONG INTCOMEDICAL PRODUCTS CO. LTD.
QIWANG ROAD, NAOSHAN INDUSTRIAL PARK
QINGZHOU
SHANDONG
262500
CHINA

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable nitrile gloves, colour blue, size 6XS, 7S,8M,9L,10XL,11XXL

TECHNICAL REPORT

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0248

WORK REQUESTED:

Samples of gloves described as Disposable nitrile gloves, colour blue, size 6XS, 7S, 8M, 9L, 10XL and 11XXL were received on the 6th October 2020 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:

Sample described as Disposable nitrile gloves, colour blue, size 6XS, 7S,8M,9L,10XL,11XXL

.

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable nitrile gloves, colour blue, size 6XS, 7S,8M,9L,10XL,11XXL achieved the following degradation results:

Chemical	Mean degradation / %
40% Sodium hydroxide (CAS: 1310-73-2)	-39.2
30% Hydrogen peroxide (CAS: 7722-84-1)	30.8
37% Formaldehyde (CAS: 50-00-0)	0.5

TESTING REQUIRED:

- EN ISO 374-4:2019. Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

SATRA TECHNOLOGY

TECHNICAL REPORT

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UKAS TESTING 0248

Sample description:	Disposable nitrile gloves, colour blue, size 6XS, 7S,8M,9L,10XL,11XXL		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-6.8	-70.1	-40.8
Mean degradation (DR) / %:	-39.2		
Standard deviation (σ_{DR}) / %:	31.7		
UoM / ± %:	13.5		
Appearance of samples after testing:	No change		

Sample description:	Disposable nitrile gloves, colour blue, size 6XS, 7S,8M,9L,10XL,11XXL		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	15.7	35.9	40.8
Mean degradation (DR) / %:	30.8		
Standard deviation (σ_{DR}) / %:	13.3		
UoM / ± %:	17.1		
Appearance of samples after testing:	Swollen and discoloured		

Sample description:	Disposable nitrile gloves, colour blue, size 6XS, 7S,8M,9L,10XL,11XXL		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	18.1	-8.0	-8.5
Mean degradation (DR) / %:	0.5		
Standard deviation (σ_{DR}) / %:	15.2		
UoM / ± %:	14.8		
Appearance of samples after testing:	No change		

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

6. EN374-5

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Test Report No.: 721655656
Report Date:1 July 2020

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	**Shandong Intco Medical Products Co., Ltd**
CLIENT ADDRESS	No.9888 Qiwang Road, Naoshan Industry Park, Qingzhou, Shandong, China
TEST PERIOD	16-Jun-2020~30-Jun-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
(Leo Liu)
Authorized Signatory

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Test Report No.: 721655656
Report Date:1 July 2020

RECEIPT DATE / TEST DATE

16-Jun-2020/ 16-Jun-2020

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

Sample Name: Medical Nitrile Examination Gloves
Sample Specification: M
Batch No./Date: 20200407
Manufacturer: Shandong Intco Medical Products Co., Ltd

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721655656	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)℃ 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 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.

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:
TÜV SÜD Certification and
Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

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Test Report No.: 721655656
Report Date:1 July 2020

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:

$$\text{ratio}=\frac{\text{control assay titer (PFU/mL)}}{\text{test material assay titer (PFU/mL)}}=1.1$$

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.

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:
TÜV SÜD Certification and
Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

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Test Report No.: 721655656
Report Date:1 July 2020

TEST RESULT(S)

Test Items		Initial titer PFU/ml	Final titer PFU/ml	Test Results				
				Step1	Step2	Step3	Assay titer (PFU/ml)	Pass/Fail
Penetration of Phi-X174 Bacteriophage	Control(+)	$1.8x10^8$	$1.8x10^8$	None Seen	Seen	-	-	Acceptable
	Control(-)	$1.8x10^8$	$1.8x10^8$	None Seen	None Seen	None Seen	<1	Acceptable
	-1	$1.8x10^8$	$1.8x10^8$	None Seen	None Seen	None Seen	<1	Pass
	-2	$1.8x10^8$	$1.8x10^8$	None Seen	None Seen	None Seen	<1	Pass
	-3	$1.8x10^8$	$1.8x10^8$	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-

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:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

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7. EN455-1

Test Report No. 7191205302-EEC19-WBH
dated 01 Mar 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 Disposable Nitrile Glove submitted by
Shandong Intco Medical Products Co., Ltd. on 18 Feb 2019.

TESTED FOR:

Shandong Intco Medical Products Co., Ltd
No. 9888 Qiwang Road
Naoshan Industry Park, Qingzhou, Shandong, China

TEST DATE:

25 Feb 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Glove	Blue	/	M	217	Shandong Intco Medical Products Co., Ltd

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

METHOD OF TEST:

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

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

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Test Report No. 7191205302-EEC19-WBH
dated 01 Mar 2019

PSB Singapore

RESULTS:

Sample: Disposable Nitrile Glove, Size M

Table: 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	0	Passed

REMARKS:

1. The manufacturing lot no. was not provided by the client.

Yeo Poh Kwang
Higher Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo : Disposable Nitrile Glove, Size M

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8. EN455-2

Test Report No.: QDHL1909015461OT Date: SEP.25,2019 Page: 1 of 3

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD
NO.9888, QIWANG ROAD, NAOSHAN INDUSTRY PARK, QINGZHOU, SHANDONG, CHINA

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

Sample Description	: METRO/MAKRO PROFESSIONAL NITRILE GLOVES, NON-POWDERED, BLUE
Sample Receiving Date	: SEP.12,2019
Testing Period	: SEP.12,2019 TO SEP.25,2019
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: EN 455-2-2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES
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.

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

Zhou Xinkuan, SK
Lab Manager

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Test Report No.: QDHL1909015461OT Date: SEP.25,2019 Page: 2 of 3

Test Conducted:

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

Number of test sample	:	26 Pieces
The type of gloves	:	examination/procedure gloves c)
Manufacturing batch code	:	/
Size	:	Examination/procedure gloves: M
Defects observed before testing	:	No defects

Clause	Test Items	Result	Note
5	Strength	---	---
5.2	Force at break	Pass	# 1
5.3	Force at break after challenge testing	Pass	# 1

Notes : #1 See result 1

Test Result:

1. **Strength**

Sample Quantity: 13pcs

Size	M												
Force at break(N)	7.8	8.5	8.0	9.0	9.4	8.9	6.8	7.1	8.2	8.9	8.3	8.6	8.4
Force at break after challenge testing(N)	7.8	7.6	8.3	7.6	6.5	6.1	8.4	7.4	6.8	6.8	8.5	7.2	6.0

Median value:

Force at break during shelf life (N): 8.4

Force at break after challenge testing (N): 7.4

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Test Report No.: QDHL1909015461OT Date: SEP.25,2019 Page: 3 of 3

Requirements: see table 3

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	**Examination/procedure gloves**	
		b)	**c)**
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 6,0	≥ 3,6

a) Requirements for all surgical gloves.
b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene)..
c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).

Sample Photo:

Received sample

SGS authenticate the photo on original report only

End of Report

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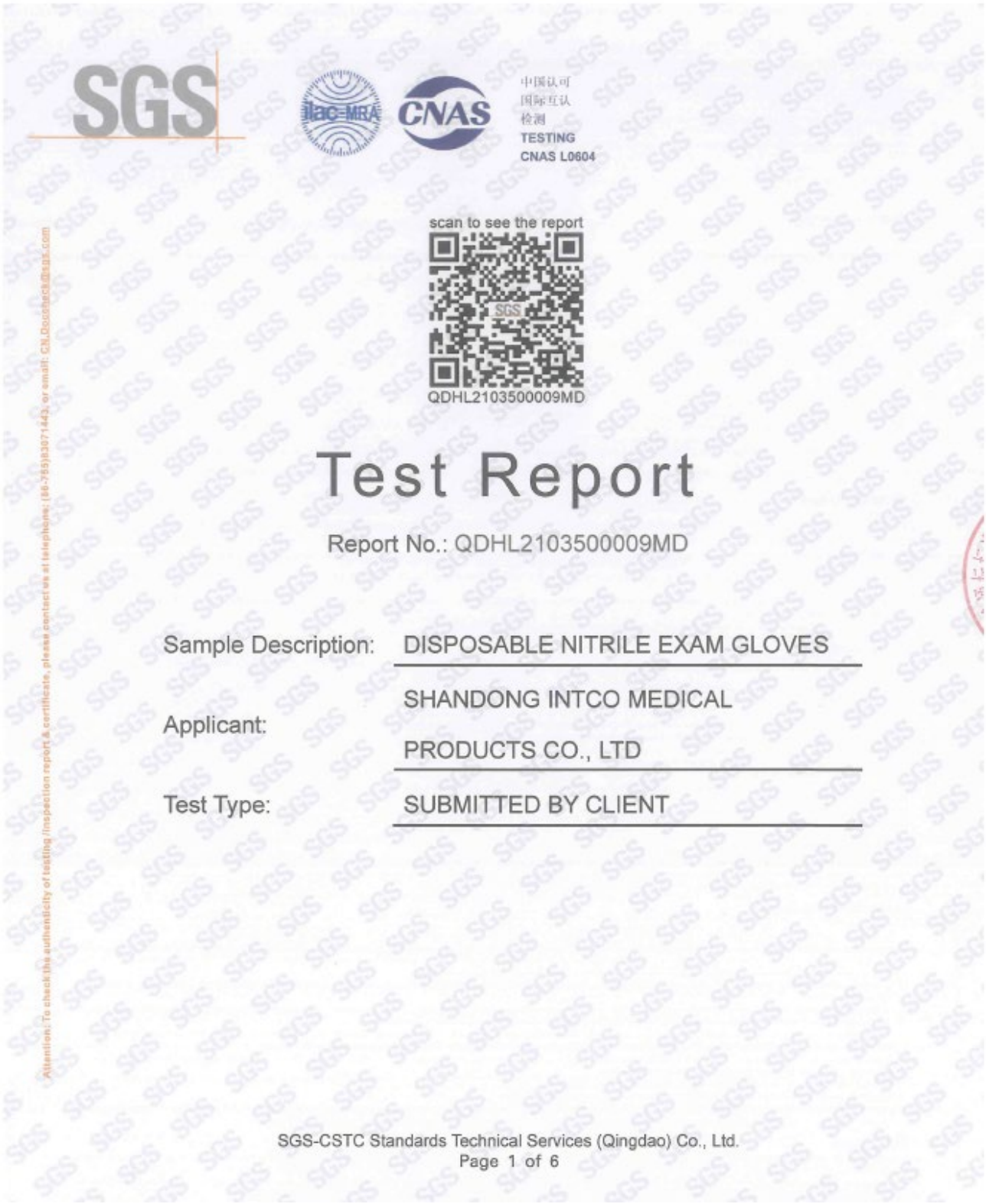
9. EN455-3



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scan to see the report

QDHL2103500009MD

Test Report

Report No.: QDHL2103500009MD

Sample Description: DISPOSABLE NITRILE EXAM GLOVES

Applicant: SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

Test Type: SUBMITTED BY CLIENT

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 1 of 6

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CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL2103500009MD

Test Report

Sample information	Sample Description	DISPOSABLE NITRILE EXAM GLOVES	Color	NOT PROVIDED
	Received sample quantity/ Tested sample quantity	10PCS/ 5PCS	Type/ Specifications	S
	Lot No.	NOT PROVIDED	Lot Quantity	NOT PROVIDED
	Manufacture Date	NOT PROVIDED	Expiration Date	NOT PROVIDED
	Material/Appearance	NOT PROVIDED	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	NOT PROVIDED		
Client information	Applicant	SHANDONG INTCO MEDICAL PRODUCTS CO., LTD		
	Applicant address	NO.9888,QIWANG ROAD,NAOSHAN INDUSTRY PARK,QINGZHOU,SHANDONG,CHINA		

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中国认可
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TESTING
CNAS L0604

Report No.: QDHL2103500009MD

Test information	Sample Receiving Date	MAR.01,2021	Test Period Date	MAR.01,2021 TO MAR.05,2021
	Sample No.	QDHL2103500009MD	Test environment	Meet requirement
	Test items	Removable surface powder		
	Testing Accordance	EN 455-3:2015 Medical Gloves for Single Use–Part 3: Requirements and Testing for Biological Evaluation clause 4.4		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: MAR.05,2021			
Remark	/			

Approver: Auditor: Compiler:

Date: 2021.03.05 Date: 2021.03.05 Date: 2021.03.05

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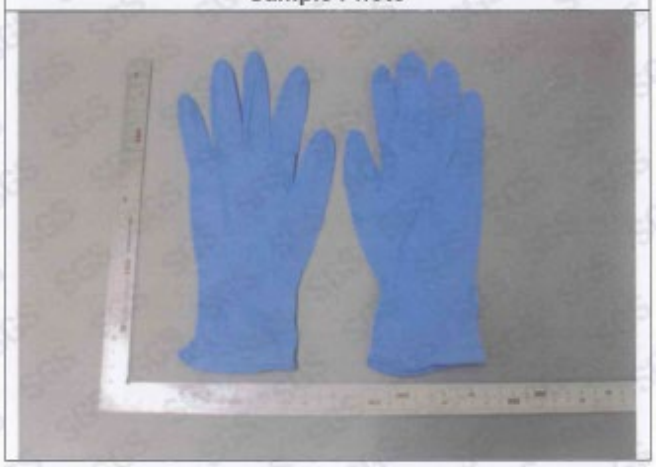
TESTING
CNAS L0604

Report No.: QDHL2103500009MD

Sample Photo



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Report No.: QDHL2103500009MD

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Removable surface powder	mg	EN 455-3: 2015 Clause 5.2 EN ISO 21171: 2006	≤2	0.22	Pass

Remarks:

1. Finish of gloves: Powdered-free gloves (As per client's requirement).
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

End of Report

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Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; no cross-page seal; altered;a copy without the red testing seal of SGS.

2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

3. 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.

4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.

5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address:
SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

Tel: 0532-68999187 Zip: 266101
Fax: 0532-80991952

E-mail: Emily.Zhang@sgs.com

10. EN455-4

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附录 D Annex D

测试数据分析&结论 Testing result analysis&conclusion

1 测试结果判定：Testing result

序号 NO.	测试项目 Item	检测结果 Testing result					
		批次 Lot 1：2015081701		批次 Lot 2：2015081702		批次 Lot 3：2015081703	
实验组 0	长度 Length	0/32	L_{Ave}=244	0/32	L_{Ave}=245	0/32	L_{Ave}=249
	厚度 Thickness	0/32	Finger T_{Ave}=0.111 Palm T_{Ave}=0.061 Cuff T_{Ave}=0.053	0/32	Finger T_{Ave}=0.113 Palm T_{Ave}=0.060 Cuff T_{Ave}=0.051	0/32	Finger T_{Ave}=0.115 Palm T_{Ave}=0.062 Cuff T_{Ave}=0.052
	物性 Physical property	0/32	F@B_{Med}=9.5 TS_{Ave}=27.7 E@B_{Ave}=580	0/32	F@B_{Med}=8.4 TS_{Ave}=24.3 E@B_{Ave}=568	0/32	F@B_{Med}=10.9 TS_{Ave}=28.5 E@B_{Ave}=625
	针孔等级 Pinhole classification	0/200		1/200		1/200	
	判定结果 Result	■合格 Qualified □不合格 Disqualified		■合格 Qualified □不合格 Disqualified		■合格 Qualified □不合格 Disqualified	
实验组 1	长度 Length	0/32	L_{Ave}=243	0/32	L_{Ave}=244	0/32	L_{Ave}=249
	厚度 Thickness	0/32	Finger T_{Ave}=0.111 Palm T_{Ave}=0.062 Cuff T_{Ave}=0.053	0/32	Finger T_{Ave}=0.113 Palm T_{Ave}=0.061 Cuff T_{Ave}=0.050	0/32	Finger T_{Ave}=0.116 Palm T_{Ave}=0.062 Cuff T_{Ave}=0.052
	物性 Physical property	0/32	F@B_{Med}=9.2 TS_{Ave}=25.0 E@B_{Ave}=541	0/32	F@B_{Med}=7.3 TS_{Ave}=23.5 E@B_{Ave}=551	0/32	F@B_{Med}=10.5 TS_{Ave}=27.5 E@B_{Ave}=606
	针孔等级 Pinhole classification	0/32		1/32		0/32	

	判定结果 Result	■合格 Qualified □不合格 Disqualified		■合格 Qualified □不合格 Disqualified		■合格 Qualified □不合格 Disqualified	
实验组2	长度 Length	L_{Ave}=244		L_{Ave}=244		L_{Ave}=249	
	厚度 Thickness	Finger T_{Ave}=0.113 Palm T_{Ave}=0.062 Cuff T_{Ave}=0.053		Finger T_{Ave}=0.113 Palm T_{Ave}=0.061 Cuff T_{Ave}=0.051		Finger T_{Ave}=0.114 Palm T_{Ave}=0.062 Cuff T_{Ave}=0.052	
	物性 Physical property	F@B_{Med}=8.6 TS_{Ave}=23.7 E@B_{Ave}=544		F@B_{Med}=6.7 TS_{Ave}=23.0 E@B_{Ave}=527		F@B_{Med}=9.1 TS_{Ave}=26.5 E@B_{Ave}=570	
	针孔等级 Pinhole classification	0/200		0/200		0/200	
	判定结果 Result	■合格 Qualified□不合格 Disqualified		■合格 Qualified □不合格 Disqualified		■合格 Qualified □不合格 Disqualified	
实验组3	长度 Length	0/32	L_{Ave}=244	0/32	L_{Ave}=244	0/32	L_{Ave}=249
	厚度 Thickness	0/32	Finger T_{Ave}=0.111 Palm T_{Ave}=0.062 Cuff T_{Ave}=0.053	0/32	Finger T_{Ave}=0.114 Palm T_{Ave}=0.061 Cuff T_{Ave}=0.050	0/32	Finger T_{Ave}=0.114 Palm T_{Ave}=0.062 Cuff T_{Ave}=0.052
	物性 Physical property	0/32	F@B_{Med}=8.7 TS_{Ave}=24.6 E@B_{Ave}=539	0/32	F@B_{Med}=7.0 TS_{Ave}=22.8 E@B_{Ave}=524	0/32	F@B_{Med}=9.0 TS_{Ave}=26.4 E@B_{Ave}=582
	针孔等级 Pinhole classification	0/32		1/32		0/32	
	判定结果 Result	■合格 Qualified □不合格 Disqualified		■合格 Qualified □不合格 Disqualified		■合格 Qualified □不合格 Disqualified	
实验组4	长度 Length	L_{Ave}=244		L_{Ave}=244		L_{Ave}=250	
	厚度 Thickness	Finger T_{Ave}=0.114 Palm T_{Ave}=0.062 Cuff T_{Ave}=0.053		Finger T_{Ave}=0.112 Palm T_{Ave}=0.061 Cuff T_{Ave}=0.051		Finger T_{Ave}=0.112 Palm T_{Ave}=0.062 Cuff T_{Ave}=0.052	
	物性 Physical	F@B_{Med}=8.3 TS_{Ave}=23.0		F@B_{Med}=6.4 TS_{Ave}=22.1		F@B_{Med}=8.7 TS_{Ave}=25.4	

	property	E@B $_{Ave}$=528	E@B $_{Ave}$=506	E@B $_{Ave}$=547
	针孔等级 Pinhole classification	0/200	0/200	0/200
	判定结果 Result	■合格 Qualified □不合格 Disqualified	■合格 Qualified □不合格 Disqualified	■合格 Qualified □不合格 Disqualified

2 物理性能测试数据分析：Physical property analysis

序号	样品批次	实验组	老化温度	老化时间	拉断力平均值	拉断强度平均值	拉断延伸率平均值
1	2015081701	实验组 0	25℃	时间 0-对照组	9.2	27.7	580
		实验组 1	70±2℃	166±2 小时	8.9	25.0	562
		实验组 2	70℃	7 天	8.5	23.7	541
		实验组 3	50±2℃	90±1 天	8.4	24.6	544
		实验组 4	50℃	120 天	8.2	23.0	528
2	2015081702	实验组 0	25℃	时间 0-对照组	8.5	24.3	568
		实验组 1	70±2℃	166±2 小时	7.4	23.5	551
		实验组 2	70℃	7 天	7.1	23.0	527
		实验组 3	50±2℃	90±1 天	7.1	22.8	524
		实验组 4	50℃	120 天	6.9	22.1	506
3	2015081703	实验组 0	25℃	时间 0-对照组	10.5	28.5	625

		实验组 1	70±2℃	166±2 小时	10.1	27.5	606
		实验组 2	70℃	7 天	9.2	26.5	570
		实验组 3	50±2℃	90±1 天	9.2	26.4	582
		实验组 4	50℃	120 天	8.9	25.4	547

分析结果：合格

4 加速老化最终测定结论 Final conclusion of accelerated aging test

符合 ASTM D7160 & EN455-4 标准