Intco Vinyl Synthetic Exam Gloves with Health Canada Approval

Glove Specifications & Packaging with Health Canada Covid-19 Interim Order Approved Device Identifier No.

BASIC Synthetic Clear Examination Gloves are made of pure virgin PVC plastics using an unique powderless process and are 100% latex free, meets or exceeds ASTM 5250.

Sizes Available		Reorder No.
X-Small	(5½ - 6)	VGPF 3000
Small	(6½ - 7)	VGPF 3001
Medium	(7½ - 8)	VGPF 3002
Large	**(8½ - 9)**	**VGPF 3003**
X-Large	(9½ -10)	VGPF 3004

CAUTION

- Storage Conditions:
  Store in a dry ventilated environment.
  Do not store above 100 F°(37C°)
- Avoid direct sunlight.
- Components used in the manufacture of gloves may cause allergic reaction in some users. Follow your institution's policies for use. Persons with known sensitivity should avoid contact.
- Gloves provide a good biological barrier and are not intended to be used as a chemical barrier.

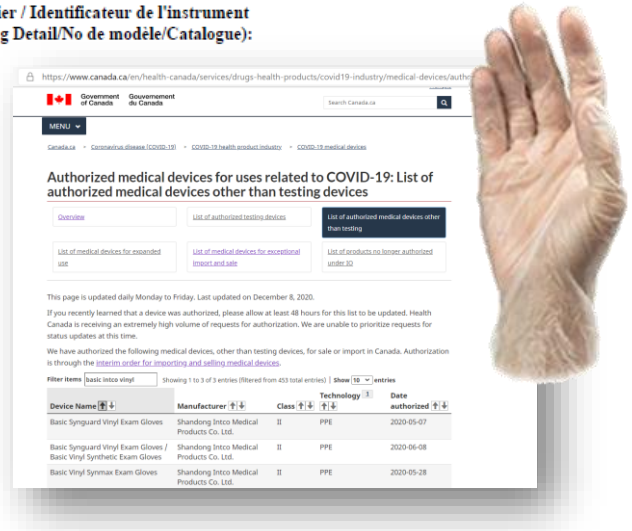
Health Canada
Santé Canada

Components/Parts/Accessories/Devices for this Lic
Les composantes, parties, accessoires et instruments médicaux pou

BASIC SYNGUARD VINYL EXAM GLOVES

Device ID/No de l'instrument: 1021491
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):

VGPF3001
VGPF3004
VGPF3003
VGPF3002



Shandong Intco Medical Products Co., Ltd.

Add:No.9888 Qiwang Road,Naoshan Industrial Park
Qingzhou,Shandong,China
Web:www.intcomedical.com
Email:[redacted]@intco.com
Tel:86[redacted]

Vinyl Disposable Gloves Product Specification

Type	Disposable Clear PVC Gloves,Powder Free						
Grade	Medical	**Surface**	Smooth	**Glove Length(mm)**	≥230		
Material	Poly-Vinyl Cloride	**Packing**	100pcs/box,10boxes/ctn	**Weight(g)**	5.0±0.3(Medium Size)		
Cuff	Beaded	**Shelf-life**	5 years	**Powder Level**	≤2mg/glove		

Product	Color	Size	Weight (g)	Physical Dimension					Physical Property			
				Length (mm)	Palm Width (mm)	Cuff Thickness (mm)	Palm Thickness (mm)	Finger Thickness (mm)	Tensile Strength(MPa)	Elongation(%)	Water Test AQL	Appearance AQL
Disposable Clear Vinyl Gloves,Powder Free	Clear	S	4.5±0.3g	≥230	85±5	0.07±0.03	0.09±0.03	0.11±0.03	⩾11	⩾300	AQL2.5	Critical AQL1.0 Major AQL2.5 Minor 4.0
		M	5.0±0.3g	≥230	95±5	0.07±0.03	0.09±0.03	0.11±0.03			AQL2.5	Critical AQL1.0 Major AQL2.5 Minor 4.0
		L	5.5±0.3g	≥230	105±5	0.07±0.03	0.09±0.03	0.11±0.03			AQL2.5	Critical AQL1.0 Major AQL2.5 Minor 4.0
		XL	6.0±0.3g	≥230	115±5	0.07±0.03	0.09±0.03	0.11±0.03			AQL2.5	Critical AQL1.0 Major AQL2.5 Minor 4.0

We has established the Quality management systerm in according with ISO9001 and ISO 13485 standards

The certification which we have is 510K ,CE certification ,ISO9001 ISO13485,

Sampling Procedures according to the standard of ISO,ASTM D5250 ,Inspection Level for pysical dimensions and force /elongation at break is according to S-2 ,water test according to G-1

Intco Vinyl Synthetic Exam Gloves with Health Canada Approval

Health Canada Covid-19 Interim Order Approval

Health Canada / Santé Canada — Medical Devices Directorate / Direction des instruments médicaux

COVID-19 Medical Device Authorization for Importation or Sale

Autorisation d'importation ou de mise en vente d'un instrument médical relatif au COVID-19

Authorization Reference Number : 316829 **Numéro de référence de l'autorisation**

Issue Date: 2020-06-08 **Date de délivrance:**

Device Class/Classe de l'instrument : 2

Pursuant to section 5 of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, made by the Minister of Health on March 18, 2020, the medical device listed below is now authorized for sale or importation in Canada.

Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of this authorization document. Please ensure to highlight the **Authorization reference number** during the import declaration process to facilitate port entry without any delays.

This authorization is only valid for so long as the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 is in effect.

Conformément à l'article 5 de *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19, réalisé par la ministre de la Santé le 18 mars 2020, les instruments indiqués ci-dessous sont présentement autorisés pour la mise en vente ou l'importation au Canada.

Tout envoi d'un instrument médical relatif au COVID-19 doit être accompagné d'une copie de la présente autorisation. Veuillez vous assurez de souligner le **numéro de référence de l'autorisation** durant le processus de déclaration d'importation pour faciliter l'entrée sans délais aux points de contrôle frontalier.

Cette autorisation est uniquement valide tant que *l'Arrêté d'urgence concernant l'importation et la vente d'instruments médicaux relatifs au Covid*-19 est en vigueur, ou l'autorisation est annulée.

Device Name(s) Nom de l'instrument

BASIC VINYL SYNTHETIC EXAM GLOVES

Name & Address of Authorization Holder/Nom & adresse du titulaire de l'autorisation

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD.
QIWANG ROAD, NAOSHAN INDUSTRIAL PARK, QINGZHOU
WEIFANG, SHANDONG
CHINA
262500

David Boudreau, ing., Interim Director General, Medical Devices Directorate
Directeur général par intérim, Direction des instruments médicaux

Application Number: / Numéro de la demande: 316829 Manufacturer ID: / Identificateur du fabricant: 139268

Health Canada / Santé Canada — Medical Devices Directorate / Direction des instruments médicaux

David Boudreau

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authoriz...

Government of Canada / Gouvernement du Canada — Search Canada.ca — MENU

Canada.ca > Coronavirus disease (COVID-19) > COVID-19 health product industry > COVID-19 medical devices

Authorized medical devices for uses related to COVID-19: List of authorized medical devices other than testing devices

Overview | List of authorized testing devices | List of authorized medical devices other than testing | List of medical devices for expanded use | List of medical devices for exceptional import and sale | List of products no longer authorized under IQ

This page is updated daily Monday to Friday. Last updated on December 8, 2020.

If you recently learned that a device was authorized, please allow at least 48 hours for this list to be updated. Health Canada is receiving an extremely high volume of requests for authorization. We are unable to prioritize requests for status updates at this time.

We have authorized the following medical devices, other than testing devices, for sale or import in Canada. Authorization is through the interim order for importing and selling medical devices.

Filter items: basic intco vinyl — Showing 1 to 3 of 3 entries (filtered from 453 total entries) | Show 10 entries

Device Name	Manufacturer	Class	Technology	Date authorized
Basic Synguard Vinyl Exam Gloves	Shandong Intco Medical Products Co. Ltd.	II	PPE	2020-05-07
Basic Synguard Vinyl Exam Gloves / Basic Vinyl Synthetic Exam Gloves	Shandong Intco Medical Products Co. Ltd.	II	PPE	2020-06-08
Basic Vinyl Synmax Exam Gloves	Shandong Intco Medical Products Co. Ltd.	II	PPE	2020-05-28

Application Number: / Numéro de la demande: 316829 Manufacturer ID: / Identificateur du fabricant: 139268

Health Canada / Santé Canada — Medical Devices Directorate / Direction des instruments médicaux

Components/Parts/Accessories/Devices for this Licence
Les composantes, parties, accessoires et instruments médicaux pour cette homologation

BASIC VINYL SYNTHETIC EXAM GLOVES

Device ID/No de l'instrument: 1022543
Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):
VGPF3001
VGPF3002
VGPF3003
VGPF3004

Application Number: / Numéro de la demande: 316829 Manufacturer ID: / Identificateur du fabricant: 139268

Intco Vinyl Synthetic Exam Gloves with Health Canada Approval

ASTM D5250-19 Test Report

Test Report No. 7191238352-EEC20-WBH
dated 29 Jun 2020

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 Gloves submitted by Shandong Intco Medical Products Co., Ltd on 03 Jun 2020.

TESTED FOR:

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

TEST DATE:

10 Jun 2020 to 26 Jun 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Vinyl Gloves	Clear	- (see remark 1)	M	273	Shandong Intco Medical Products Co., Ltd

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

METHOD OF TEST:

ASTM D5250-19 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
- Clauses 6.1.2 & 7.3 Freedom from Holes (Cross-reference to Test Method D5151)
- Clauses 6.1.3 & 7.4 Physical Dimensions Test
- Clauses 6.1.4 & 7.5 Physical Requirements Test – Die C, accelerated aging conducted according to Clause 7.5.2: 70±2°C for 72±2h (Cross-reference to Test Method D412 and D573)
- Clauses 6.1.5 & 7.6 Powder Free Gloves (Cross-reference to Test Method D6124)

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

Test Report No. 7191238352-EEC20-WBH
dated 29 Jun 2020

PSB Singapore

RESULTS:

Sample: Disposable Vinyl Gloves, Clear, Size M

Table 1: Results for Freedom from Holes

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
6.1.2 7.3	Freedom from holes	Shall not leak	10	200	3	Passed

Table 2: Results for Physical Dimensions Test

Clause	Tests	Require-ments (mm)	Results (mm)			Number of pieces			Inferred results
			Min.	Mean	Max.	Non-compliers allowed	Tested	Actual non-compliers found	
6.1.3 7.4	a) Width	For size M: 95 ± 10	94	96	97	1	13	0	Passed
	b) Length	For size M: ≥ 230	239	241	242				
	c) Finger thickness	≥ 0.08	0.14	0.15	0.16				
	d) Palm thickness	≥ 0.08	0.10	0.10	0.10				

Table 3: Results for Physical Requirements Test – before accelerated aging

Clause	Tests	Require-ments	Results			Number of pieces			Inferred results
			Min.	Mean	Max.	Non-compliers allowed	Tested	Actual non-compliers found	
6.1.4 7.5	Tensile strength (MPa)	≥ 11	17	19	20	1	13	0	Passed
	Ultimate elongation (%)	≥ 300	338	375	394				

Table 4: Results for Physical Requirements Test – after accelerated aging

Clause	Tests	Require-ments	Results			Number of pieces			Inferred results
			Min.	Mean	Max.	Non-compliers allowed	Tested	Actual non-compliers found	
6.1.4 7.5	Tensile strength (MPa)	≥ 11	17	19	20	1	13	0	Passed
	Ultimate elongation (%)	≥ 300	338	370	403				

Intco Vinyl Synthetic Exam Gloves with Health Canada Approval

ASTM D5250-19 Test Report

RESULTS (cont'd):

Sample: Disposable Vinyl Gloves, Clear, Size M

Table 5: Results for Powder Free Gloves

Clause	Tests	Requirements	Result	Inferred Results
6.1.5 7.6	Powder-free gloves	Powder residue ≤ 2.0 mg	0.05 mg per glove	Passed

REMARKS:

1. The manufacturing batch code was not provided by client.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Disposable Vinyl Gloves, Clear, Size M

Test Report No. 7191238352-EEC20-WBH
dated 29 Jun 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

Intco Vinyl Synthetic Exam Gloves with Health Canada Approval

ASTM F1671 PhiX174 Bacteriophage Test

ORIGINAL

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	18-Dec-2017~29-Dec-2017
TEST REQUEST	Penetration of Phi-X174 Bacteriophage Test - with reference to ASTM F 1671-2013

Prepared By

(Gao Ju)
Report Drafter

Authorized By

(Chen Wei)
Authorized Signatory

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

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

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

ORIGINAL

RECEIPT DATE / TEST DATE

18-Dec-2017/ 18-Dec-2017

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

Sample Name: Vinyl Gloves
Sample Type: /
Sample Batch: /
Manufactory: Shandong Intco Medical Products Co., Ltd.

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721636611	Sample in the plastic bag	

TEST METHOD(S)

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

REQUIREMENT

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

TEST ORGANISM(S)

Bacteriophage ATCC 13706-B1

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
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Fax : +86 (21) 6037 6345
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Regional Head Office:
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No.151 Heng Tong Road Shanghai
200 070 P.R.China

ORIGINAL

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.

TEST RESULT(S)

Test Items		Initial titer PFU/ml	Final titer PFU/ml	Test Results				
				Step1	Step2	Step3	Assay titer (PFU)	Pass/Fail
Penetration of Phi-X174 Bacteriophage	Control(+)	1.8x10^8	1.7x10^8	None Seen	Seen	-	-	Acceptable
	Control(-)	1.8x10^8	1.7x10^8	None Seen	None Seen	None Seen	<1	Acceptable
	-1	1.8x10^8	1.7x10^8	None Seen	None Seen	None Seen	<1	Pass
	-2	1.8x10^8	1.7x10^8	None Seen	None Seen	None Seen	<1	Pass
	-3	1.8x10^8	1.7x10^8	None Seen	None Seen	None Seen	<1	Pass

Note: PFU: Plaque Forming Unit.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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200 070 P.R.China

Intco Vinyl Synthetic Exam Gloves with Health Canada Approval

ISO 9001:2015, ISO 13485:2016 and MDSAP Audit Certification

intertek
Total Quality. Assured.

CERTIFICATE
OF REGISTRATION

This is to certify that the management system of:

Shandong Intco Medical Products Co., Ltd.

Qiwang Road, Naoshan Industrial Park, Qingzhou City, Shandong Province, P. R. China

has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

Manufacture of disposable non sterile NBR (Nitrile Butadiene Rubber) and PVC (Poly Vinyl Chloride) gloves.

Unified Social Credit Identifier:
91370781561439654L

Certificate Number:
111812005

Initial Certification Date:
27 January 2013

Date of Certification Decision:
03 January 2019

Issuing Date:
03 January 2019

Valid Until:
27 January 2022

UKAS MANAGEMENT SYSTEMS
014

Calin Moldovean
President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.
The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.

intertek
Total Quality. Assured.

CERTIFICATE
OF REGISTRATION

This is to certify that the management system of:

Shandong Intco Medical Products Co., Ltd.

Main Site: Qiwang Road, Naoshan Industrial Park, Qingzhou City, Shandong Province, 262500 P.R. China

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Manufacture of non-sterile NBR (Nitrile Butadiene Rubber) and PVC (Poly Vinyl Chloride) patient examination gloves.

Certificate Number:
0086238

Initial Certification Date:
28 April 2014

Certificate Issue Date:
17 January 2019

Certificate Expiry Date:
31 December 2021

SCC Accredited CB-MS
OCSM Accredité CCN

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.
CT-ISO 13485_2016-SCC-EN-A4-01.Jul.17

intertek
Total Quality. Assured.

CERTIFICATE
OF REGISTRATION

This is to certify that the management system of:

Shandong Intco Medical Products Co., Ltd.

(DUNS # 42-128-5853)

Main Site: Qiwang Road, Naoshan Industrial Park, Qingzhou City, Shandong Province, 262500 P.R. China

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Manufacture of non-sterile NBR (Nitrile Butadiene Rubber) and PVC (Poly Vinyl Chloride) patient examination gloves.

Certificate Number:
0086239

Initial Certification Date:
2019-01-25

Certification Effective Date:
2019-01-25

Certification Expiry Date:
2022-01-24

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

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CT-MDSAP-2016-NA-EN-LT-P-30.apr.18

Intco Vinyl Synthetic Exam Gloves with Health Canada Approval

Retail Box and Outer Carton Packaging

公司名称	YKYL	尺寸	230*125*60mm	制图人	HYBZ
物料名称	内盒	材质	300g白卡覆亮膜	制图日期	2020/03/06
产品号	F005A-00	色号	C+M+Y+K+186C+1280C+430C	确认人	
型号	L	版本		确认日期	

公司名称	YKYL	尺寸	315*258*245mm	制图人	HYBZ
物料名称	外箱	材质	三层白板300g面纸 (single wall white)	制图日期	2020/05/19
产品号	F005A-00	色号	K+186C	确认人	
型号	L	版本		确认日期	

Intco Vinyl Synthetic Exam Gloves with Health Canada Approval

Genuine access to Intco via official communication channels

回复: RE: 4*40HQ containers clear vinyl gloves available in Dec

S [redacted]@intco.com>

To [redacted]

Cc [redacted]

Reply | Reply All | Forward | ...

Wed 2020-12-09 11:24 AM

ISO9001：2015 Qingzhou factory.pdf 534 KB

2019年 ISO13485 新版证书.pdf 345 KB

ASTM D5250 Clear Vinyl 2020-07.02.pdf 164 KB

Dear [redacted],

Please kindly find the attached certification you want.

Best regards,
Solina

[redacted]
Senior Sales
INTCO Medical

+86 [redacted] (office)
+86 [redacted] (cell)
[redacted]@intco.com

Our official email address suffix ends with @intco.com. It's the only email address we have.

Intco Vinyl Synthetic Exam Gloves with Health Canada Approval

Sample sent directly from Intco Factory