Intco Synmax Blended Vinyl Nitrile Exam Gloves with Health Canada Approval

Glove Specifications & Packaging with Health Canada Covid-19 Interim Order Approval

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

Device Name	Manufacturer	Class	Technology [1]	Date authorized
Basic Vinyl Synmax Exam Gloves	Shandong Intco Medical Products Co. Ltd.	II	PPE	2020-05-28

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 SYNMAX EXAM GLOVES

Device ID/No de l'instrument: 1022102
Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):
BMPF3001
BMPF3002
BMPF3003
BMPF3004

Shandong Intco Medical Products Co., Ltd.

Add:No.9888 Qiwang Road,Naoshan Industrial Park
Qingzhou,Shandong,China
Web:www.intcomedical.com

Vinyl Disposable Gloves Product Specification

Type	Disposable Blue Synmax Vinyl Gloves,Powder Free					
Grade	Medical	**Surface**	Smooth	**Glove Length(mm)**	≥230	
Material	Poly-Vinyl Cloride+ NBR LATEX	**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: Length (mm)	Palm Width (mm)	Cuff Thickness (mm)	Palm Thickness (mm)	Finger Thickness (mm)	Physical Property: Tensile Strength(MPa)	Elongation(%)	Water Test AQL	Appearance AQL
Disposable Blue Synmax Vinyl Gloves,Powder Free	Blue	S	4.5±0.3g	≥230	85±5	0.07±0.03	0.09±0.03	0.11±0.03	≥13	≥350	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 Synmax Blended Vinyl Nitrile 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 :	315664	**Numéro de référence de l'autorisation**
Issue Date:	2020-05-28	**Date de délivrance:**
Amendment Date:	2021-01-21,	**Date de modification:**
Reason for Amendment	Correction to Device Class	**Raison de la modification**

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 SYNMAX 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

Application Number: / Numéro de la demande: 315664 — Manufacturer ID: / Identificateur du fabricant: 139268

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

262500

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


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

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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 IO

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: 315664 — 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 SYNMAX EXAM GLOVES

Device ID/No de l'instrument: 1022102
Device Identifier / Identificateur de l'instrument (Model/Catalog Detail/No de modèle/Catalogue):
BMPF3001
BMPF3002
BMPF3003
BMPF3004

Application Number: / Numéro de la demande: 315664 — Manufacturer ID: / Identificateur du fabricant: 139268

Intco Synmax Blended Vinyl Nitrile Exam Gloves with Health Canada Approval

ASTM D5250-19 Test Report

SGS

Test Report No.: QDHL2004002960MD-01 Date: SEP.22,2020 Page: 1 of 5

THIS REPORT IS TO SUPERSEDE TEST REPORT NO.: QDHL2004002960MD, DATE: APR.29,2020. THE ORIGINAL REPORT SHALL BECOME INVALID AS OF THE DATE OF ISSUANCE OF THIS REPORT.

Client name	:	SHANDONG INTCO MEDICAL PRODUCTS CO.,LTD
Client address	:	NO.9888,QIWANG ROAD,NAOSHAN INDUSTRY PARK,QINGZHOU,SHANDONG,CHINA
Sample Description	:	SYNMAX VINYL EXAM GLOVES▲
Lot No.	:	NOT PROVIDED
Lot Size	:	NOT PROVIDED
Sample Quantity	:	280PCS

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.14,2020
Test Performing Date	:	APR.14,2020 TO APR.29,2020
Test Performed	:	SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	:	ASTM D 5250-19 STANDARD SPECIFICATION FOR POLY (VINYL CHLORIDE) GLOVES FOR MEDICAL APPLICATION (CLAUSE 6.1.2, 6.1.3, 6.1.4, 6.1.5)
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.

Jessica Gao
Approved Signatory

scan to see the report

QDHL2004002960MD-01

SGS

Test Report No.: QDHL2004002960MD-01 Date: SEP.22,2020 Page: 2 of 5

Test Conducted:

ASTM D 5250-19 Standard Specification for Poly (vinyl chloride) Gloves for Medical Application

Number of test sample	:	231 Piece(s)

Clause	Test Items	Result	Note
6.1.2	Freedom from holes	Pass	#1
6.1.3	Physical dimensions	Pass	#2
6.1.4	Physical property characteristics	Pass	#3
6.1.5	Powder residue for powder free gloves	Pass	#4

Notes :
#1 See result 1
#2 See result 2
#3 See result 3
#4 The average mass of powder per glove is 0.04mg (Requirement: ≤ 2.0mg)

Test Result:

Result 1: Freedom from Holes

Sample Quantity: 200 Ac: 10 Re: 11 Found: 0

Intco Synmax Blended Vinyl Nitrile Exam Gloves with Health Canada Approval

ASTM D5250-19 Test Report

Result 2: Physical dimensions

Sample Quantity: 13 Ac: 1 Re: 2 Found: 0

Sample No.	Size: M			
			Median value/mm	
	Length/mm	Width/mm	Thickness-finger	Thickness-palm
1	238	96	0.082	0.091
2	237	98	0.094	0.098
3	237	98	0.092	0.092
4	240	96	0.093	0.097
5	232	97	0.092	0.096
6	236	98	0.092	0.097
7	230	96	0.094	0.093
8	234	96	0.083	0.095
9	235	97	0.081	0.094
10	239	98	0.113	0.093
11	240	97	0.092	0.095
12	242	98	0.135	0.091
13	239	98	0.143	0.095
Standard requirement	≥230	95±5	≥0.08	≥0.08
Found	0	0	0	0

Result 3: Physical property characteristics

Sample Quantity: 13 Ac: 1 Re: 2 Found: 0

Force at break before aging

Sample No.	Size: M	
	Tensile strength (Mpa)	Ultimate Elongation (%)
1	16	313
2	16	394
3	17	344
4	19	364
5	18	365
6	20	395
7	19	372
8	17	346
9	21	404
10	18	349
11	18	365
12	19	366
13	19	368
Standard requirement	≥11	≥300
Found	0	0

Force at break after aging

Sample No.	Size: M	
	Tensile strength (Mpa)	Ultimate Elongation (%)
1	19	370
2	20	409
3	18	382
4	19	374
5	20	378
6	18	356
7	16	347
8	19	360
9	18	372
10	16	307
11	18	368
12	17	340
13	18	357
Standard requirement	≥11	≥300
Found	0	0

Remark:
1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
2. The marked ▲ part is the modification information.

Sample Photo:

SGS authenticate the photo on original report only

End of Report

Intco Synmax Blended Vinyl Nitrile Exam Gloves with Health Canada Approval

ASTM D6499 Test Report for The Immunological Measurement of Antigenic Protein

ARDL
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

October 20, 2020

▪TEST REPORT▪

PN 156280
Check

CHEMICAL ANALYTICAL SERVICES

Prepared For:

Cecily Sheng
Intco Medical Industries Inc.
805 Barrington Avenue
Ontario CA 91764

Prepared By: _____
Erin Samples, Sr. Technician, Microbiology
Chemical/Analytical Services

Approved By: _____
Ana Barbur, Vice President
Chemical/Analytical Services

Rev 110119

A2LA ACCREDITED

An A2LA ISO 17025 Accredited Testing Laboratory – Certificate Numbers 255.01 & 256.02
ISO 9001-2015 Registered

ISO 9001:2015 Registered

ARDL
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

SUBJECT: Analytical testing on samples submitted by the above referenced customer

RECEIVED: One (1) glove sample identified as Blue Powder Free Synmax Size M Gloves

Decision Rule 1

ASSAY PROCEDURE:
Sample Extractions. The sample was weighed, measured, and cut prior to extraction within a polypropylene extraction vessel. The extraction buffer used was 50 mM phosphate pH 7.4 at a ratio 5 ml of buffer per gram of sample. The extraction was carried out at room temperature for two hours with agitation. The sample was removed and the extract centrifuged at 500 xg for 15 minutes to pellet particulates. The cleared extract was then used in the assay.

ASTM D6499 ELISA Inhibition Assay. The standard and test samples are serially diluted in a 96 well plate, after which an equal volume of diluted rabbit anti-latex polyclonal antibody is added and the plate incubated for 2h at 37°C. One hundred microliters of sample from each well is transferred to the corresponding well of a plate coated with Hevea NRL and blocked with non-fat dry milk and incubated for 2h at 37°C. The plates are then washed and a 100 µl solution of Goat anti-Rabbit IgG conjugated with the enzyme HorseRadish Peroxidase (HRP) is added and incubated for 1h at 37°C. Plates are washed and a 100-µl solution of the substrate OPD is added to each well and color allowed to develop. The reaction is stopped by the addition of 50 µl of 4N H_2SO_4. The plate is then read at 490 nm. Protein values are determined by interpolation from a standard curve.

RESULTS: The sample identified as Blue Powder Free Synmax Size M Gloves tested below the detection limit of the assay at ≤0.2 µg/gm and ≤0.1 µg/dm².

ASTM D6499 Test Certificate

Sample Description	Weight (gm)	Area (dm²)	Extract Vol. (ml)	Assay Conc. (µg/ml)	Antigenic Protein (µg/gm)		Antigenic Protein (µg/dm²)	
Blue Powder Free Synmax Size M Gloves	4.9	8.7	24.5	b.d.	<	0.2	<	0.1

Where b.d.= below detection, (0.03 µg/ml)

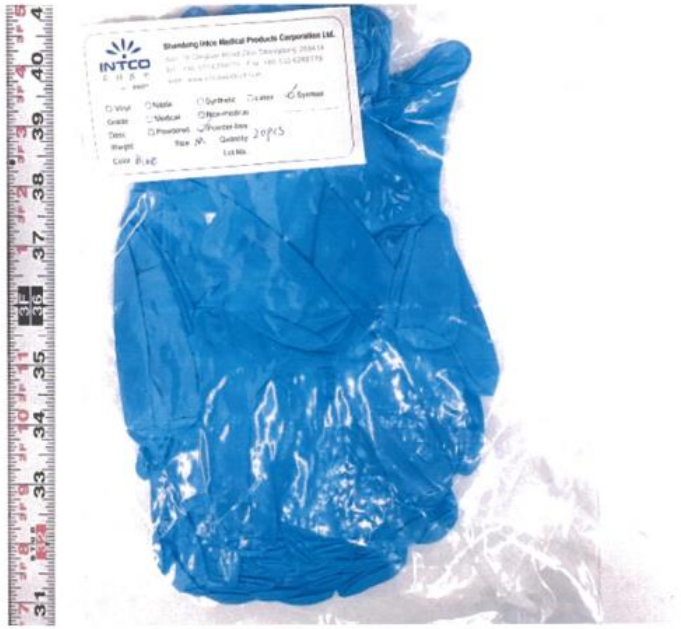
*Note: *The results given in this report relate only to the items tested. This report cannot be reproduced except in full without the written consent of ARDL.*

**ARDL is ISO 17025 accredited by A2LA for the test methods listed on the certificates referenced on page one. Unless specified, the current specification version is used.*
NOTE: Non-ISO 17025 accredited test methods are designated with the ^ symbol to differentiate from ISO 17025 accredited methods in the body of the test report.*

www.ardl.com | 2887 Gilchrist Rd. | Akron, Ohio 44305 | answers@ardl.com | Toll Free (800) 830-ARDL
Fax (330) 794-6610 | Worldwide (330) 794-6600

Intco Synmax Blended Vinyl Nitrile Exam Gloves with Health Canada Approval

ASTM D6499 Test Report for the Immunological Measurement of Antigenic Protein



Sample – Blue Glove Powder Free Synmax Size M

Decision Rules

Rule 1. This is the way test results have traditionally been reported by ARDL. If ARDL runs a test for you that has pass/fail requirements, ARDL will report the values observed and then state "Pass" or "Fail", based on those values only. By default, ARDL will apply this rule to all Category I tests and those tests which are not on ARDL's Scope of Accreditation.

Rule 2. This rule takes into account the calculated measurement uncertainty of test results generated. Every test and piece of test equipment has an inherent amount of measurement uncertainty associated with it. Rule 2 establishes "Guard Bands" where the measurement uncertainty value is added to the Minimum Passing requirement and is subtracted from the Maximum Passing requirement. The Pass/Fail requirements thus become tighter and customers may be more "Certain" of their Pass/Fail result.

Rule 3. This rule also takes into account measurement uncertainty but does not set up guard bands. Rule 3 may be used when values are reported, but there is no Pass/Fail requirement called out in the test specification. Rule 3 simply states that the measurement uncertainty is reported to the customer, along with the testing result generated, and the customer decides if the results are suitable for their purposes.

Report Revision Log

Date	Report Revision	Description
10-20-20	New	

Prepared By: **Erin Samples, Sr. Technician, Microbiology**
Chemical/Analytical Services

Approved By: **Ana Barbur, Vice President**
Chemical/Analytical Services

ES/AB/tkr

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Intco Synmax Blended Vinyl Nitrile Exam Gloves with Health Canada Approval

ASTM D1671 Test Report for Penetration of Phi-X174 Bacteriophage

SUBJECT	**Microbiological Test**
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-Nov-2020~25-Nov-2020
TEST REQUEST	Penetration of Phi-X174 Bacteriophage Test - with reference to ASTM F1671/F1671M-2013

Prepared By

Wei Jun
(Wei Jun)
Report Drafter

Authorized By

(Den Liu)
Authorized Signatory

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
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Phone : +86 (21) 6037 6375
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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

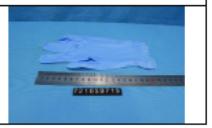
Test Report No. : 721659719-1
Report Date: 26 November 2020

RECEIPT DATE / TEST DATE

16-Nov-2020/ 16-Nov-2020

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

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

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721659719	Blue disposable gloves	

TEST METHOD(S)

Penetration of Phi-X174 Bacteriophage Test
- with reference to ASTM F1671/F1671M-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

Retaining Screen:Stainless steel mesh screen
Diameter of the steel wire : 0.80mm
Retaining Screen pore: 2.0mm*2.0mm
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:
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ASTM D1671 Test Report for Penetration of Phi-X174 Bacteriophage

1.5. Prepare a control by adding a 2.0 µL aliquot from the same suspension directly into 5.0 mL of sterile bacteriophage nutrient broth.
1.6. After 60 min, quantitatively assay by adding 5.0mL of sterile bacteriophage nutrient broth onto the surface of the specimen.
1.7. Calculate the ratio of the control assay titer to the test material assay titer using the following equation:

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

1.8. Record the initial titer of the Phi-X174 bacteriophage challenge suspension used for the test . ($(2\pm1)\times10^8$ 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.

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Test Report No. : 721659719-1
Report Date: 26 November 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(+)	1.8×10^8	1.7×10^8	None Seen	Seen	-	-	Acceptable
	Control(-)	1.8×10^8	1.7×10^8	None Seen	None Seen	None Seen	<1	Acceptable
	-1	1.8×10^8	1.7×10^8	None Seen	None Seen	None Seen	<1	PASS
	-2	1.8×10^8	1.7×10^8	None Seen	None Seen	None Seen	<1	PASS
	-3	1.8×10^8	1.7×10^8	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:
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Glove Specifications & Packaging with Health Canada Covid-19 Interim Order Approval

Applications

- Medical Purpose / Examination
- Industrial purpose / PPE
- Laboratory
- Healthcare and nursing
- General housekeeping
- IT Industry

SKU	Size	Color	Package	Box Size	Carton Dimension
SGBEM1001*	S-XL	Blue	100pcs/box,10boxes/ctn	230*125*60mm	315*258*245mm
SGBEM1002*	S-XL	White	100pcs/box,10boxes/ctn	230*125*60mm	315*258*245mm
SGBEM1003*	S-XL	Violet	100pcs/box,10boxes/ctn	230*125*60mm	315*258*245mm

※ The last "*" means Size:4-S 5-M 6-L 7-XL.

Synmax Blended Vinyl Nitrile Exam Gloves with Health Canada Approval

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

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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.

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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 Synmax Blended Vinyl Nitrile 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

INTCO 英科医疗

[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