Intco Basic SynGuard Nitrile Medical Examination Glove

Basic SynGuard Nitrile Examination Glove Health Canada Covid-19 Interim Approval - MDEL #12101

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> Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19

> Exceptional importation and sale of medical devices in relation to COVID-19: Overview

List of medical devices for exceptional importation and sale

Overview | List of designated medical devices

Medical devices included on this list are called "**designated medical devices**" and are eligible for the exceptional importation and sale provisions provided for in the Interim Order.

Supersedes: 2020-10-23
Date issued: 2020-10-27

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Filter items Basic Synguard — Showing 1 to 1 of 1 entries (filtered from 240 total entries) | **Show** 10 **entries**

List of Medical Devices for Exceptional Importation and Sale

Medical Device	Medical Device Category	Country of Manufacture	Name of Manufacturer	MDEL/MDL number	Date
Basic Synguard Nitrile Exam Gloves	II	China	Shandong Intco Medical Products Co., Ltd.	MDEL 12101	2020-08-21

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Date modified: 2020-10-27

Shandong Intco Medical Products Co., Ltd.

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

Nitrile Disposable Gloves Product Specification

Type	Blue Nitrile Gloves,Powder Free						
Grade	Medical	**Surface**	Smooth	**Glove Length(mm)**	≥230		
Material	NBR Latex	**Packing**	100pcs/box,10boxes/ctn	**Weight(g)**	3.3±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 Blue Nitrile Gloves, Powder Free	Blue	XS	2.8±0.3g	≥230	70±10	0.07±0.03	0.08±0.03	0.08±0.03	≥14	≥500	AQL1.5	Critical AQL1.0 Major AQL2.5 Minor 4.0
		S	2.9±0.3g	≥230	80±10	0.07±0.03	0.08±0.03	0.08±0.03			AQL1.5	Critical AQL1.0 Major AQL2.5 Minor 4.0
		M	3.3±0.3g	≥230	95±10	0.07±0.03	0.08±0.03	0.08±0.03			AQL1.5	Critical AQL1.0 Major AQL2.5 Minor 4.0
		L	3.5±0.3g	≥230	110±10	0.07±0.03	0.08±0.03	0.08±0.03			AQL1.5	Critical AQL1.0 Major AQL2.5 Minor 4.0
		XL	4.1±0.3g	≥230	120±10	0.07±0.03	0.08±0.03	0.08±0.03			AQL1.5	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 ,ISO9001 ISO13485

Sampling Procedures according to the standard of ISO13485,ASTM D6319, ASTM D6978 ,ASTM F1671 Inspection Level for pysical dimensions and force /elongation at break is according to S-2 ,water test according to G-1

Intco Basic SynGuard Nitrile Medical Examination Glove

Basic SynGuard Nitrile Examination Glove Health Canada Covid-19 Interim Approval - MDEL #12101

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 : 315622 **Numéro de référence de l'autorisation**

Issue Date: 2020-05-15 **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

SYNGUARD NITRILE 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

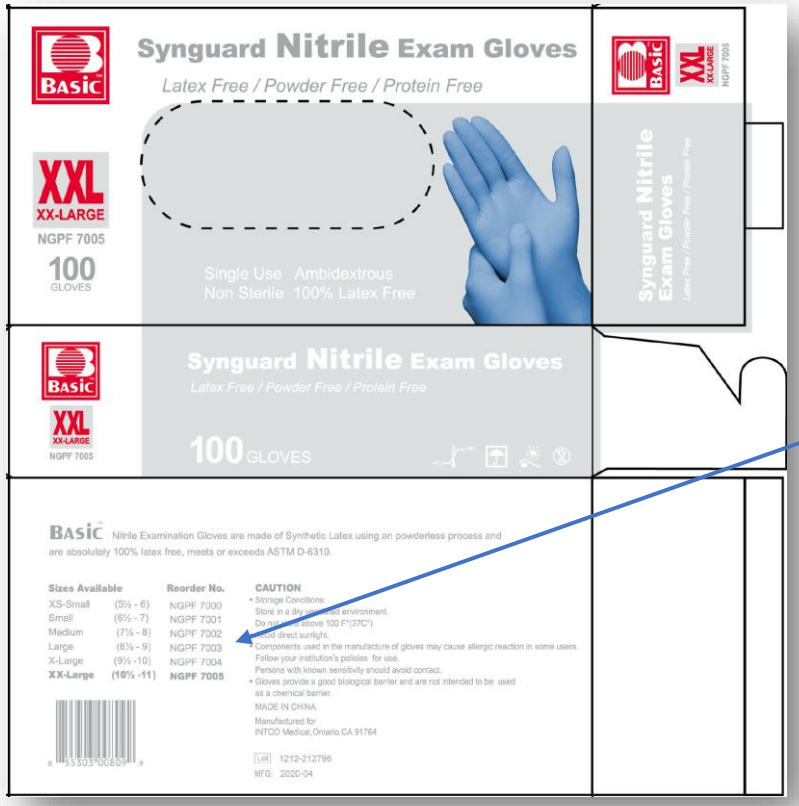
Application Number: / Numéro de la demande: 315622

Manufacturer ID: / Identificateur du fabricant: 139268

Health Canada
Santé Canada

Medical Devices Directorate
Direction des instruments médicaux

David Boudreau



Application Number: / Numéro de la demande: 315622

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

SYNGUARD NITRILE EXAM GLOVES

Device ID/No de l'instrument: 1021684
Device Identifier / Identificateur de l'instrument
(Model/Catalog Detail/No de modèle/Catalogue):
NGPF7000
NGPF7001
NGPF7002
NGPF7003
NGPF7004
NGPF7005

Health Canada Device Identifier on Retail Box

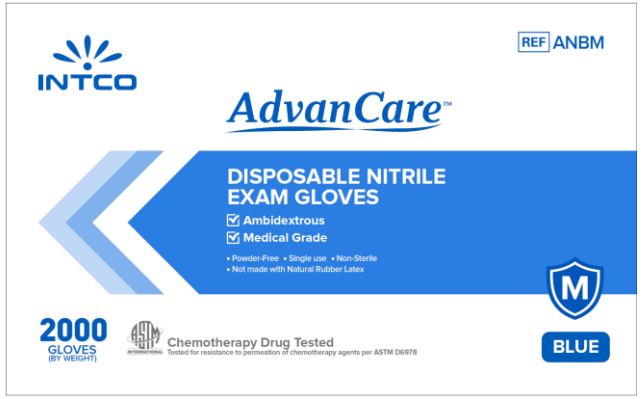
Application Number: / Numéro de la demande: 315622

Manufacturer ID: / Identificateur du fabricant: 139268

Intco Nitrile Medical Examination Glove New Nitrile US Packaging with Chemo Drug Tested

Canadian Special Order with MCL, Basic Synguard Nitrile Examination Glove
Special Edition with Chemo Drug Test validated by Intco 100 pcs / box

US AdvanCare
Brand Packaging
200 pcs / box



INTCO **SHANDONG INTCO MEDICAL PRODUCTS CO.,LTD**

QIWANG ROAD, NAOSHAN CHEMICAL INDUSTRY PARK, QINGZHOU SHANDONG CHINA
Tel: 0536-6136888 Fax:0536-6136999

Mar 03, 2021

Statement

To whom it may concern,

We, SHANDONG INTCO MEDICAL PRODUCTS CO., LTD hereby to declare that
we will use the basic brand packaging pack the chemo grade gloves for MCL Chemical LTD, the gloves can pass the ASTM D6978 and ASTM F1671. And INTCO brand 200*10 packaging's Health Canada register will finish in next 2-3 weeks, at that time we will recheck the packaging then.
Basic brand packaging pictures are as below:

INTCO Brand 200*10 packaging pictures are as below:

Yours sincerely,
SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

Intco Basic SynGuard Nitrile Medical Examination Glove

FDA Registration & 510(k)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&regNum=&StateName=

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

1 result found for **Owner Operator Number :**
10048737

New Search

Establishment Name		Registration Number	Current Registration Yr
SHANDONG INTCO MEDICAL PRODUCTS CO LTD	CHINA	3011391433	2021
• Polymer Patient Examination Glove - NITRILE POWDER-FREE EXAMINATION GLOVES TESTED FOR USE WITH CHEMOTHERAPY DRUGS			Contract Manufacturer; Manufacturer
• Polymer Patient Examination Glove - Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, And Tested For Use With Chemotherapy Drugs			Contract Manufacturer; Manufacturer
• Patient Examination Glove, Specialty - Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, And Tested For Use With Chemotherapy Drugs			Contract Manufacturer; Manufacturer
• Polymer Patient Examination Glove - Esteem Stretchy Nitrile Powder-Free Exam Gloves			Contract Manufacturer; Manufacturer
• Vinyl Patient Examination Glove - Vinyl Patient Examination Glove			Contract Manufacturer
• Show all 7 Listings For *SHANDONG INTCO MEDICAL PRODUCTS CO LTD CHINA*			

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https://www.accessdata.fda.gov/cdrh_docs/pdf/K990186.pdf

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Attachment A

Page___of___

510(k) Number (if known): K990186

Device Name: Shanghai INTCO Plastic Rubber Products Co., Ltd.
Synthetic Powderfree Nitrile Patient Examination Gloves

Indications For Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examinaer's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Chin S. Lin
(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K990186

Intco Basic SynGuard Nitrile Medical Examination Glove

ASTM D6319 Test Report

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	: DISPOSABLE NITRILE EXAM GLOVES
Lot No.	: NOT PROVIDED
Lot Size	: NOT PROVIDED
Sample Quantity	: 256PCS
Storage Condition	: ROOM TEMPERATURE
Sample Receiving Date	: MAY.11,2020
Testing Period	: MAY.11,2020 TO MAY.26,2020
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: ASTM D6319-2019 STANDARD SPECIFICATION FOR NITRILE EXAMINATION GLOVES FOR MEDICAL APPLICATION (CLAUSE 5, 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 REQUESTED 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

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Test Conducted:

ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application

Number of test sample	:	231 Piece(s)

Clause	Test Items	Result
5	Sampling	See Result 1
6	Performance Requirements	---
6.1.2	Freedom from Holes	Pass (See Result 2)
6.1.3	Physical dimensions	Pass (See Result 3)
6.1.4	Physical property characteristics	Pass (See Result 4)
6.1.5	Powder Residue For Powder Free Gloves	Pass (See Result 5)

Test Result:

Result 1: Sampling

The number of specimen:

	Sample size	Ac	Re
Freedom from Holes	200	10	11
Dimensions	13	1	2
Physical property	13	1	2

Result 2: Freedom from Holes

Sample Quantity: 200pcs

AQL=2.5 Ac: 10 Re: 11 Found: 3

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Intco Basic SynGuard Nitrile Medical Examination Glove

ASTM D6319 Test Report

Result 3: Physical dimensions

Sample Quantity: 13pcs

AQL=4.0 Ac:1 Re: 2

Sample No.	Size: M			
	Length/mm	Width/mm	Median value/mm	
			Thickness-finger	Thickness-palm
1	242	98	0.084	0.074
2	240	98	0.079	0.073
3	249	99	0.074	0.078
4	247	97	0.088	0.079
5	237	97	0.095	0.078
6	247	98	0.077	0.080
7	245	98	0.089	0.079
8	245	98	0.094	0.079
9	247	98	0.078	0.074
10	245	97	0.088	0.081
11	247	98	0.088	0.086
12	240	98	0.087	0.081
13	246	98	0.081	0.073
Standard requirement	≥230	95±10	≥0.05	≥0.05
Found	0	0	0	0

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Result 4: Physical property characteristics

Sample Quantity: 13pcs

AQL=4.0 Ac: 1 Re: 2

Size: M					
Before Aging			After Aging		
Sample No.	Tensile strength (Mpa)	Ultimate Elongation (%)	Sample No.	Tensile strength (Mpa)	Ultimate Elongation (%)
1	28.10	584	1	29.79	603
2	24.94	555	2	23.52	552
3	28.42	579	3	28.07	586
4	23.83	580	4	29.00	604
5	23.79	579	5	24.98	576
6	30.28	583	6	30.09	577
7	24.60	593	7	22.94	553
8	31.13	603	8	29.92	600
9	24.53	588	9	22.84	560
10	23.94	570	10	26.09	589
11	26.28	589	11	28.07	593
12	33.20	598	12	29.28	599
13	28.74	584	13	32.87	591
Standard requirement	≥14	≥500	Standard requirement	≥14	≥400
Found	0	0	Found	0	0

Result 5: Powder Residue For Powder Free Gloves

The average mass per glove(mg)	0.12
Standard requirement(mg)	≤2.0

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

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Sample Photo:

Received sample

SGS authenticate the photo on original report only

End of Report

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Intco Basic SynGuard Nitrile Medical Examination Glove

ASTM D5712 Natural latex free testTest Report

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

THIS REPORT IS TO SUPERSEDE TEST REPORT NO.SHAHG1926089101

Sample Name: Disposable Nitrile Gloves

Above information and sample(s) was/were submitted and confirmed by the client. SGS, however, assumes no responsibility to verify the accuracy, adequacy and completeness of the sample information provided by client.

****

SGS Job No.: QDHL1911018592MD-01

Date of sample received: 25 Nov. 2019

Testing Period: 25 Nov. 2019 – 02 Dec. 2019

Test Requested: Selected test (s) as requested by client.

Test Method: Please refer to next page(s).

Test Results: Please refer to next page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Helen Liu
Approved Signatory

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Summary of Results:

Test Item	Test Method	Result	Conclusion
Natural Latex Identification	FTIR, PY-GCMS, UV-VIS	See results	/

Note: Pass: Meet the requirements;
Fail: Does not meet the requirements;
/: Not apply to the judgment.

Test Item: Natural Latex Identification
Sample Description: See Photo
Test Method:
1: Major composition check: With reference to ASTM E1252-98(2013), analysis was performed by Fourier Transform Infrared Spectrometer(FTIR);
2: Major composition check: With reference to ISO 17257:2013, analysis was performed by Pyrolysis Gas Chromatography Mass Spectrometry(PY-GCMS);
3: Determination of aqueous extractable protein: With reference to ASTM D5712-15, analysis was performed by Ultraviolet and Visible Spectrometry (UV-VIS);

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Test Result:

Test Item	Result
Major composition check by FTIR	Major composition is Acrylonitrile-butadiene rubber
Major composition check by PY-GCMS	Major composition is Acrylonitrile-butadiene rubber
Determination of aqueous extractable protein(μg/ml)	Not detected

Remark:
1: μg/ml = microgram per milliliter
2: Detection limit of aqueous extractable protein is 2μg/ml

Conclusion:
As per test specified above, the submitted sample was found to be material Acrylonitrile-butadiene rubber. It was not made of natural latex.

Remark:
1: Natural latex contain poly(isoprene) and aqueous extractable protein.
2: Per US FDA recommendation dated on 2015 March, it is recommended not to state the wording "NOT CONTAIN latex" and the wording "Free of latex" in any medical devise.

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Intco Basic SynGuard Nitrile Medical Examination Glove

ASTM D5712 Natural latex free testTest Report

Representative attachments

1: FTIR

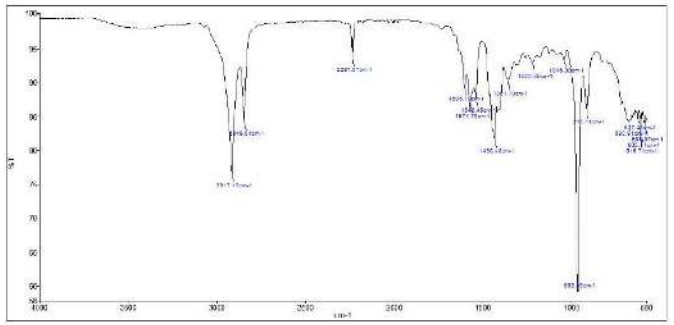

Fig.1

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Sample photo:

SHA19-260891.001

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Intco Basic SynGuard Nitrile Medical Examination Glove

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	Qiwang Road, Naoshan Industry Park, Qingzhou, Shandong, China
TEST PERIOD	15-Apr-2016~28-Apr-2016
TEST REQUEST	Penetration of Phi-X174 Bacteriophage Test - with reference to ASTM F 1671-2013

Prepared By

(Zhu Yichen)
Customer Service

Authorized By

(Spark Shi)
Technical Manager

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

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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

15-Apr-2016/ 15-Apr-2016

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

Sample Name: Blue nitrile glove
Sample Type: M
Sample Batch: /
Manufactory: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721625235	Blue glove	

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.
   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.

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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:
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 . ($(2\pm1)\times10^8$ 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.

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(+)	1.7×10^8	1.7×10^8	None Seen	Seen	-	-	Acceptable
	Control(-)	1.7×10^8	1.7×10^8	None Seen	None Seen	None Seen	<1	Acceptable
	-1	1.7×10^8	1.7×10^8	None Seen	None Seen	None Seen	<1	Pass
	-2	1.7×10^8	1.7×10^8	None Seen	None Seen	None Seen	<1	Pass
	-3	1.7×10^8	1.7×10^8	None Seen	None Seen	None Seen	<1	Pass

Note:
PFU: Plaque Forming Unit.

-END OF THE TEST REPORT-

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Intco Basic SynGuard Nitrile Medical Examination Glove

ASTM D6978 Chemical Drugs Test Report

ARDL
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

October 30, 2019

▪TEST REPORT▪

PN 149986B

PHARMACEUTICAL SERVICES

Prepared For:

John Zhao
Intco Medical Industries Inc.
805 Barrington Avenue
Ontario, CA 91764

Prepared By: _____ Approved By: _____

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Ana C Barbur, M.S.
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Rev 101218

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ARDL
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

October 30, 2019

SUBJECT: Permeation testing per ASTM D 6978 on gloves submitted by the above company.

RECEIVED: One (1) glove type identified as; Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

TEST CHEMICALS:

Table 1.1 List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	TEVA; Lot# 313219068; Expiration 09/2019 (Tested prior to exp.)
Busulfan, 6 mg/ml (6,000 ppm)	Sigma; Lot# BCBS8240V; Expiration 12/2021
Cetuximab, 2 mg/ml (2,000 ppm)	Lilly; Lot# C1700079; Expiration 04/2020
Cisplatin, 1 mg/ml (1,000 ppm)	Accord; Lot# PY02454; Expiration 04/2021
Cyclosporin A, 100 mg/ml (100,000 ppm)	USP; Lot# J0M382; Expiration 11/2019
Cytarabine, 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# LRAB3688; Expiration 12/2021
Dacarbazine, 10 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Daunorubicin, 5 mg/ml (5,000 ppm)	Sigma Aldrich; Lot# 125M4750V; Expiration 03/2020
Docetaxel, 10 mg/ml (10,000 ppm)	Sigma Aldrich; Lot# LRAB0750; Expiration 12/2021
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	WestWard; Lot# BJ0044; Expiration 10/2020
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	Actavis; Lot 7U15152; Expiration 10/2020
Fludarabine, 25 mg/ml (25,000 ppm)	USP; Lot# H1K220; Expiration 12/2019
Idarubicin, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# R080E0; Expiration 12/2019
Melphalan, 5 mg/ml (5,000 ppm)	USP; Lot# R086P0; Expiration 04/2021
Methotrexate, 25 mg/ml (25,000 ppm)	Mylan; Lot# 7801774; Expiration 04/2020
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma Aldrich; Lot# MKCD6056; Expiration 03/2020
Paraplatin (Carboplatin), 10 mg/ml (10,000 ppm)	TEVA; Lot# 18F06MA; Expiration 06/2020
Retrovir, 10 mg/ml (10,000 ppm)	GlaxoSmithKline; Lot# C819185; Expiration 04/2020
Rituximab, 10 mg/ml (10,000 ppm)	Hetero Healthcare; Batch# RB1921B; Expiration 08/2021
Topotecan, 1 mg/ml (1,000 ppm)	USP; Lot# R093L0; Expiration 11/2020
Trisenox, 1 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# 129K0039V; Expiration 12/2020

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Deviation from Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff Area

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Intco Basic SynGuard Nitrile Medical Examination Glove

ASTM D6978 Chemical Drugs Test Report

COLLECTION MEDIA:

Table 2 Collection Media for Test Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	Distilled Water
Busulfan, 6 mg/ml (6,000 ppm)	Distilled Water
Cetuximab, 2 mg/ml (2,000 ppm)	Distilled Water
Cisplatin, 1 mg/ml (1,000 ppm)	Distilled Water
Cyclosporin A, 100 mg/ml (100,000 ppm)	Distilled Water
Cytarabine, 100 mg/ml (100,000 ppm)	Distilled Water
Dacarbazine, 10 mg/ml (10,000 ppm)	Distilled Water
Daunorubicin, 5 mg/ml (5,000 ppm)	Distilled Water
Docetaxel, 10 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	Distilled Water
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	Distilled Water
Fludarabine, 25 mg/ml (25,000 ppm)	Distilled Water
Idarubicin, 1 mg/ml (1,000 ppm)	Distilled Water
Melphalan, 5 mg/ml (5,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Paraplatin (Carboplatin), 10 mg/ml (10,000 ppm)	Distilled Water
Retrovir, 10 mg/ml (10,000 ppm)	Distilled Water
Rituximab, 10 mg/ml (10,000 ppm)	Distilled Water
Topotecan, 1 mg/ml (1,000 ppm)	Distilled Water
Trisenox, 1 mg/ml (1,000 ppm)	Distilled Water

DETECTION METHOD OF CHEMICAL PERMEATION:

UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3 Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	290
Busulfan, 6 mg/ml (6,000 ppm)	197
Cetuximab, 2 mg/ml (2,000 ppm)	199
Cisplatin, 1 mg/ml (1,000 ppm)	199
Cyclosporin A, 100 mg/ml (100,000 ppm)	199
Cytarabine, 100 mg/ml (100,000 ppm)	272
Dacarbazine, 10 mg/ml (10,000 ppm)	320
Daunorubicin, 5 mg/ml (5,000 ppm)	269
Docetaxel, 10 mg/ml (10,000 ppm)	231
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	232
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	233 & 253
Fludarabine, 25 mg/ml (25,000 ppm)	261
Idarubicin, 1 mg/ml (1,000 ppm)	257
Melphalan, 5 mg/ml (5,000 ppm)	260
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Paraplatin, 10 mg/ml (10,000 ppm)	192
Retrovir, 10 mg/ml (10,000 ppm)	266
Rituximab, 10 mg/ml (10,000 ppm)	192
Topotecan, 1 mg/ml (1,000 ppm)	254
Trisenox, 1 mg/ml (1,000 ppm)	197

SAMPLE CHARACTERISTICS:

Table 4 Cuff thickness for glove identified as: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Bleomycin Sulfate	0.068	0.062	0.066	0.065
Busulfan	0.066	0.058	0.069	0.064
Cetuximab	0.060	0.069	0.065	0.065
Cisplatin	0.063	0.073	0.062	0.066
Cyclosporin A	0.065	0.064	0.066	0.065
Cytarabine	0.065	0.065	0.063	0.064
Dacarbazine	0.067	0.064	0.068	0.066
Daunorubicin	0.067	0.061	0.068	0.065
Docetaxel	0.065	0.063	0.068	0.065
Doxorubicin HCl	0.061	0.066	0.070	0.066
Epirubicin HCl (Ellence)	0.068	0.065	0.075	0.069
Fludarabine	0.072	0.074	0.063	0.070
Idarubicin	0.068	0.065	0.073	0.068
Melphalan	0.056	0.061	0.065	0.060
Methotrexate	0.064	0.062	0.081	0.069
Mitomycin C	0.060	0.071	0.068	0.066
Paraplatin	0.056	0.068	0.064	0.063
Retrovir	0.060	0.064	0.064	0.063
Rituximab	0.073	0.063	0.075	0.070
Topotecan	0.073	0.066	0.063	0.067
Trisenox	0.074	0.068	0.063	0.069
Weight/Unit Area (g/m²)	**64.4**			

RESULTS:

Table 5 Permeation Test Results on Testing of: Disposable Exam Nitrile Gloves, Blue Color, Powder-Free, Non-sterile, Lot# ISCT201907.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Busulfan, 6 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cetuximab, 2 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cisplatin, 1 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclosporin A, 100 mg/ml (100,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cytarabine, 100 mg/ml (100,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Daunorubicin, 5 mg/ml (5,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Docetaxel, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Epirubicin HCl (Ellence), 2 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fludarabine, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Idarubicin, 1 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Melphalan, 5 mg/ml (5,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paraplatin, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Retrovir, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Rituximab, 10 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Topotecan, 1 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Trisenox, 1 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

Intco Basic SynGuard Nitrile Medical Examination Glove

EN455-1 Test Report

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

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

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

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.
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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 Basic SynGuard Nitrile Medical Examination Glove

EN455-2 Test Report

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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t (86-532) 68999888 f (86-532) 80991955 e sgs.china@sgs.com
Member of the SGS Group (SGS SA)

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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t (86-532) 68999888 f (86-532) 80991955 e sgs.china@sgs.com
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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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Intco Basic SynGuard Nitrile Medical Examination Glove

EN455-3 Test Report

Test Report No.: SHHG1512047994MD Date: DEC. 09, 2015 Page: 1 of 3

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD
QIWANG ROAD, NAOSHAN INDUSTRY PARK, QINGZHOU, SHANDONG, CHINA

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

Sample Description	: NITRILE GLOVES
SGS Ref. No.	: QDHG1512005952OT
Sample Receiving Date	: DEC. 03, 2015
Testing Period	: DEC. 03, 2015 TO DEC. 09, 2015
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: POWDER (EN 455-3-2006 MEDICAL GLOVES FOR SINGLE USE—PART 3:REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION CLAUSE 4.4)
Test Result(s)	: FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	: THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

****

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Vincent Feng
Technical Manager

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Member of the SGS Group (SGS SA)

Test Report No.: SHHG1512047994MD Date: DEC. 09, 2015 Page: 2 of 3

Test Conducted:

EN 455-3-2006 Medical gloves for single use—Part 3:Requirements and testing for biological evaluation

Number of test sample	:	5 Pieces
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
4.4	Powder	Pass	#1

Note:
1. Test according to EN ISO 21171-2006.
2. The quantity of powder was 0.2mg<2mg.

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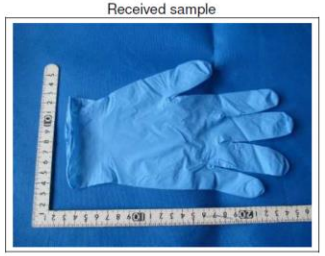
Test Report No.: SHHG1512047994MD Date: DEC. 09, 2015 Page: 3 of 3

Sample Photo:

Received sample



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Intco Basic SynGuard Nitrile Medical Examination Glove

EN455-3 Test Report

SGS

Material and Engineering Laboratory-Kaohsiung

Test Report

Report No. : KV-18-11251
Page No. : 1 OF 2
Date of Report : Dec. 25, 2018

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

Product Name	Disposable Nitrile Glove (QDHL1811025521OT)
Date of Sample Received	Dec. 10, 2018
Date of Testing	Dec. 10, 2018~Dec. 25, 2018
Remark	The information mentioned in the above section is provided by Client(Exclude Date of Sample Received and Date of Testing)

The laboratory tests according to the test requests and samples provided by client, and the results are as follows:

Test Request : Aqueous Extractable Protein

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

Test Result : Please see attached pages

----- 1 -----

The required specification(s) offered in this test report is/are for reference only.
The conformity judgment is at the Applicant's final verdict.

Signed for and on behalf of
SGS Taiwan Ltd.

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TWC5824033
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2007

SGS

Material and Engineering Laboratory-Kaohsiung

Test Report

Report No. : KV-18-11251
Page No. : 2 OF 2
Date of Report : Dec. 25, 2018

Test Equipment :

Name	Brand	Model
UV-VISIBLE Spectrophotometer	SHIMADZU	UV-1700

Lab. Environmental Conditions:

Ambient Temperature : (25 ± 2) ℃
Relative humidity : (50 ± 10) %

Test Result :

INSPECTION ITEM	TEST RESULT
Aqueous Extractable Protein (ppm)	n.d.

Note: 1. n.d. = not detected.
2. MDL (METHOD DETECTION LIMIT):0.2ppm.

Sample Photo :

----- oOo -----

The required specification(s) offered in this test report is/are for reference only.
The conformity judgment is at the Applicant's final verdict.

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Intco Basic SynGuard Nitrile 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

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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

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CT-ISO 13485_2016-SCC-EN-A4-01,jul.17

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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 Basic SynGuard 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]

ISO9001：2015 Qingzhou factory.pdf 534 KB
2019年 ISO13485 新版证书.pdf 345 KB
ASTM D5250 Clear Vinyl 202 164 KB

Dear [redacted],

Please kindly find the attached certification you want.

Best regards,
[redacted]

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 addres

SHANDONG INTCO MEDICAL PRODUCTS CO.,LTD
QIWANG ROAD, NAOSHAN CHEMICAL INDUSTRY PARK, QINGZHOU SHANDONG CHINA
Tel: 0536-6136888 Fax:0536-6136999

Mar 03, 2021

Statement

To whom it may concern,

We, SHANDONG INTCO MEDICAL PRODUCTS CO., LTD hereby to declare that
we will use the basic brand packaging pack the chemo grade gloves for MCL Chemical LTD, the gloves can pass the ASTM D6978 and ASTM F1671. And INTCO brand 200*10 packaging's Health Canada register will finish in next 2-3 weeks, at that time we will recheck the packaging then.
Basic brand packaging pictures are as below:

Synguard Nitrile Exam Gloves
Latex Free / Powder Free / Protein Free
X-Large
Item Number.
NGPF 7004
NGPF 7004

INTCO Brand 200*10 packaging pictures are as below:

AdvanCare DISPOSABLE NITRILE EXAM GLOVES
2000 BLUE

Yours sincerely,
SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

1

Intco Basic Synguard Nitrile Exam Gloves with Health Canada Approval

Samples sent directly from Intco factory in Zibo, Shandong, China

EXPRESS WORLDWIDE WPX DHL

2021-01-13 XMLPI 6.2 / *90-1604*

From : Shandong Intco Medical Product
[redacted]
Qilu Chemical Industry Park
Zibo,Shandong,China
255414 LINZI,ZIBO
CHINA,PEOPLES REPUBLIC

Origin: TAO

Contact: [redacted]

Contact:
14168931520

To : Malcolm Chiu
Malcolm Chiu
Unit 1011, 24 Wellesley Street West
Toronto, Ontario
Canada
M4Y 2X TORONTO
Canada

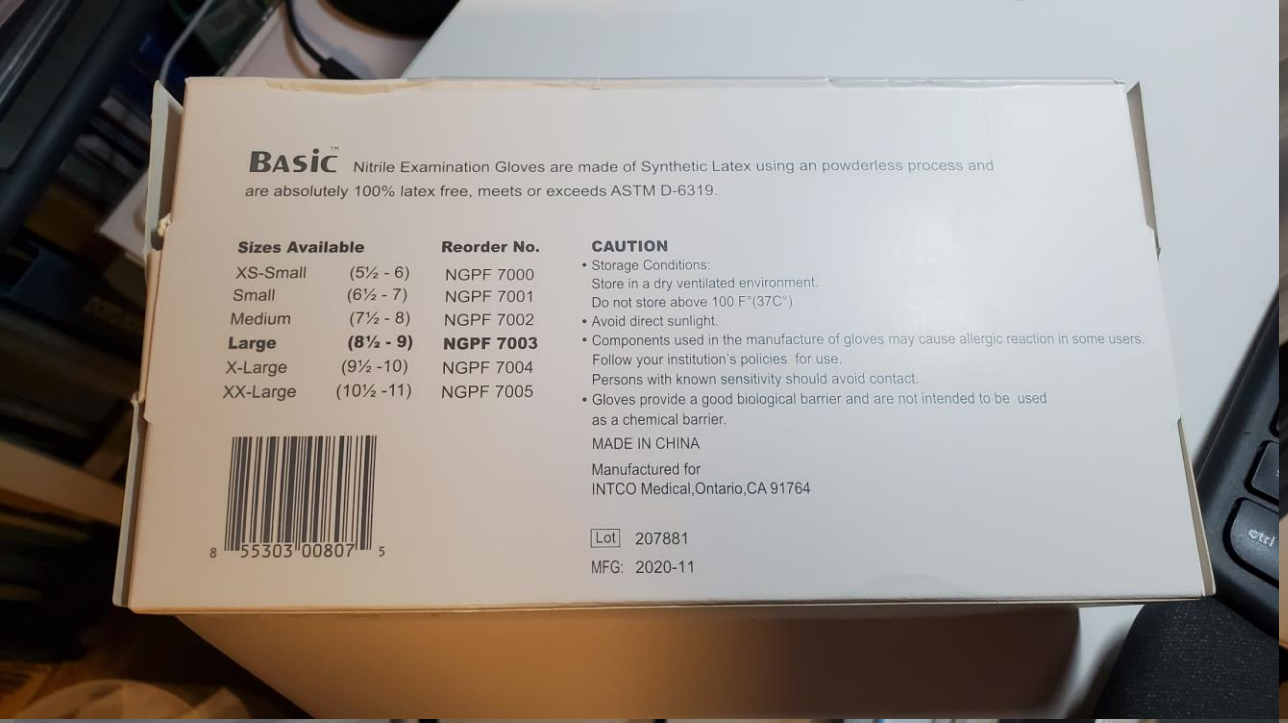
CA-YHM-YTZ

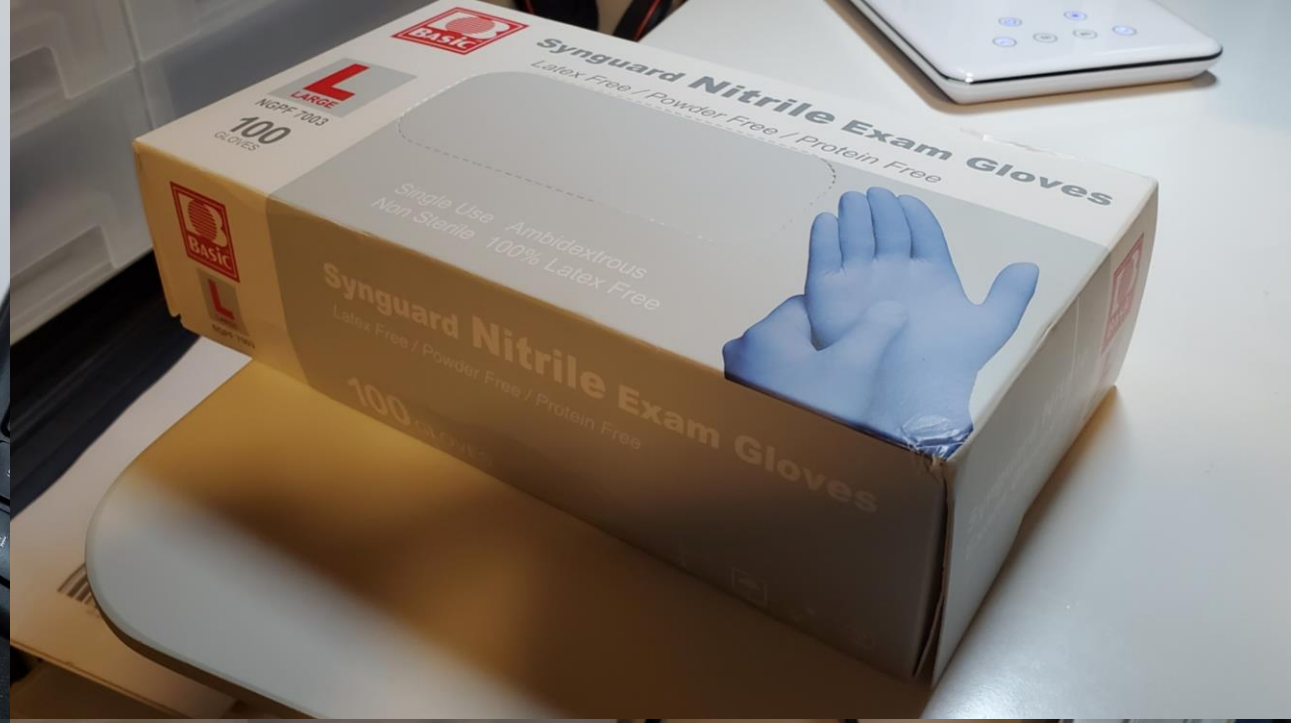
C

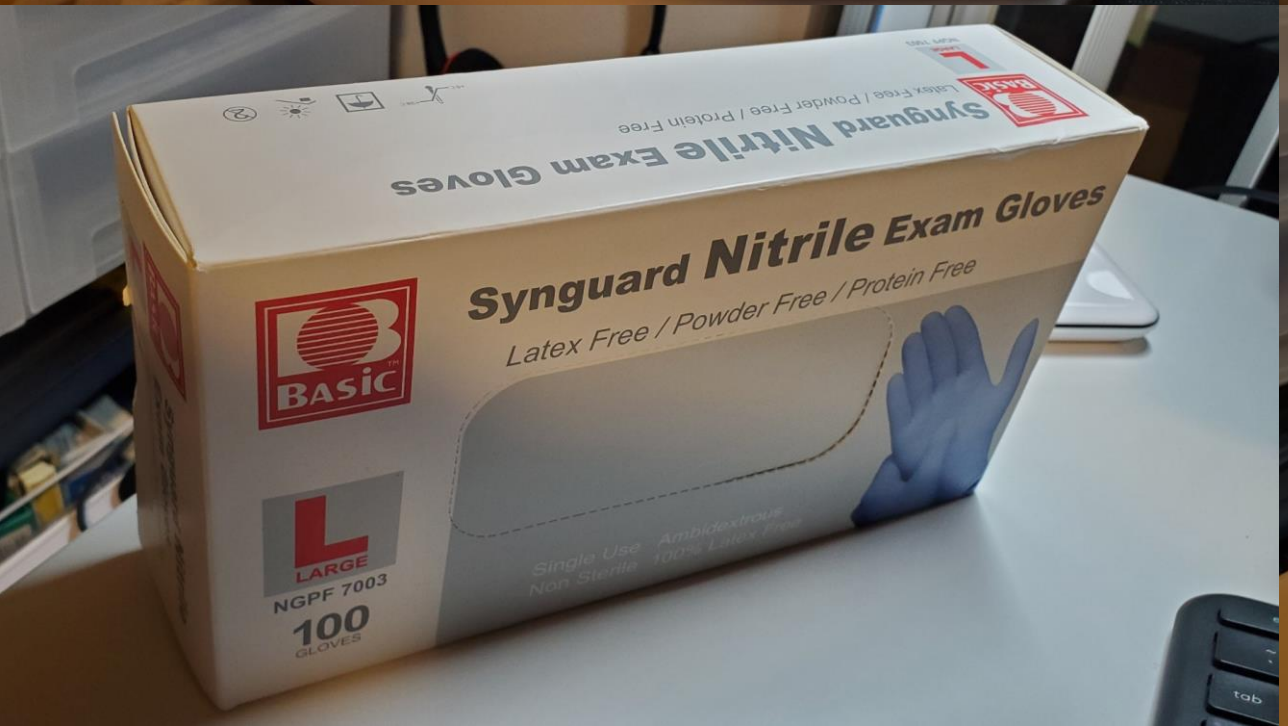
Day Time

Ref:

Pce/Shpt Weight Piece
0.5 kg 1/1


BASIC™ Nitrile Examination Gloves are made of Synthetic Latex using an powderless process and are absolutely 100% latex free, meets or exceeds ASTM D-6319.
Sizes Available
Reorder No.
XS-Small (5½ - 6) NGPF 7000
Small (6½ - 7) NGPF 7001
Medium (7½ - 8) NGPF 7002
Large (8½ - 9) NGPF 7003
X-Large (9½ -10) NGPF 7004
XX-Large (10½ -11) NGPF 7005
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.
MADE IN CHINA
Manufactured for
INTCO Medical,Ontario,CA 91764
Lot 207881
MFG: 2020-11
8 55303 00807 5


BASIC
L
LARGE
NGPF 7003
100
GLOVES
Synguard Nitrile Exam Gloves
Latex Free / Powder Free / Protein Free
Single Use Ambidextrous
Non Sterile 100% Latex Free


BASIC
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LARGE
NGPF 7003
100
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CAUTION