# 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.

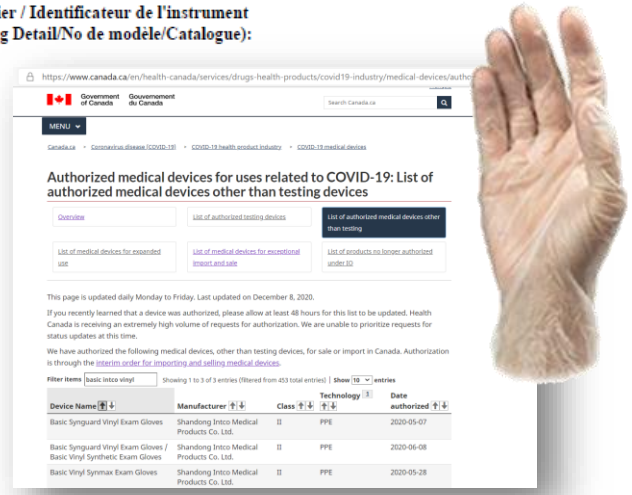
Health Canada
Santé Canada

**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 :** 314376 **Numéro de référence de l'autorisation**

**Issue Date:** 2020-05-07 **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 SYNGUARD VINYL 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: 314376 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: 314376 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 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

Application Number: / Numéro de la demande: 314376 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<br>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

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

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. Validity of this certificate may be verified at http://www.intertek.com/business-assurance/certificate-validation/
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+428C+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.**