COVID-19
PPE & Medical Equipment

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Hand Protection - Vinyl Gloves

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT
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Shield Works PPE

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Nick Cunningham QVCS
President & Founder
Major in HM Royal Marines (ret'd)

Mark Jacobs
CEO
1st Class Mechanical Engineer

Mark Clayton FMATT
CFO
Vice-Chairman of British Chamber of Commerce Guangdong;
2019 Peace Laureate

SHIELD WORKS
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Hand Protection - Vinyl Gloves

Vinyl Gloves

- DOP, DEHP-free
- Available both powder-free and powdered
- Practical barrier for wide range of applications
- Soft, good fit, feel and performance
- Available in sizes from XS to XL

Quality Standard

Complies with EN 455 AND EN 374

Complies with ASTM D5250

SKU: SW-VIGLV

Packaging details
100 pcs per carton / 1000 pcs per box
Carton Size: 33.5 x 26.5 x 26.5 cm
G.W.: 6 KG
CBM: 0.02 KG
V.W.: 4.7 KG

CE FDA

Certifications

FDA

CE

Type	Powder-free, unsterile
Material	Vinyl
Color	Transparent
Model	Ambidextrous, with rolled rim
Storage	Protect from heat, humidity, strong light and ozone
Size/overall length as per EN 455-2	XS, S, M, L and XL 240 mm (≥230mm for USA)
Impermeability as per EN 455-1	AQL 1.5, 2.5, 4.0 Available
Durability, in original package if stored as per din 7716, ISO 2230	Min. 5 years

SHIELD WORKS
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Hand Protection - Vinyl Gloves

U.S. FOOD & DRUG ADMINISTRATION

June 20, 2019

Anhui Intco Medical Products Co. Ltd
℅ Derek Tian
Official Correspondent
Intco Medical Industries, Inc.
805 Barrington Ave
Ontario, California 91764

Re: K190095
Trade/Device Name: Powder-Free Clear Vinyl Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: March 21, 2019
Received: March 26, 2019

Dear Derek Tian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
THT4B2: Disinfection, Reprocessing and Personal Protection
Acting Assistant Director, THT4B1: Sterility Devices
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Vinyl Gloves

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190095

Device Name

Powder-free clear vinyl patient examination gloves

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiners' hands or fingers to prevent contamination between patients and examiners

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Hand Protection - Vinyl Gloves

SATRA TECHNOLOGY

Issued to:

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

Notified Body: 2777

SATRA customer number: P1720

EU Type-Examination Certificate

Certificate number: 2777/11030-03/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

Clear – 697024575 XXX
Yellow – 697024575 XXX
Blue – 697024575 XXX
White – 697024575 XXX

Size	Blue	White	Clear	Yellow
6 XS	221	231	201	211
7 S	222	232	202	212
8 M	223	233	203	213
9 L	224	234	204	214
10 XL	225	235	205	215

Description:

Disposable vinyl Powdered and Powder-Free, non-sterile gloves

Classification:

EN ISO 374-1:2016/Type B	Level	Degradation %
Sodium Hydroxide 40% (K)	6	-19.9
Hydrogen peroxide 30%(P)	2	22.1
Formaldehyde 37% (T)	3	19.2
EN ISO 374-5:2016		
Protection against bacteria and fungi	Pass	
Protection against viruses	Pass	

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN 388:2016; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:
SGS: CH:TX:7420016049, CH:TX:7420016055,QDHL1703003987OT, QDHL1703003988OT, CH:TX: 9420028491-1, CH:TX:9420028490, CH:TX:1042061966, CH:TX:1042059408
SATRA: CHT0272448/1814. CHT0285339/1921, CHT0280247/1903
TUV: 721642857-1, 719223458-EEC19-WBH_CR1, 7191221099-CHM19-TSL

Signed on behalf of SATRA: Anita Brennan — Anita Brennan — Jacque Glasspool

Date first issued: 06/08/2018
Date of issue: 09/01/2020

Expiry date: 06/08/2023

Hand Protection - Vinyl Gloves

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

SHIELD WORKS
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Hand Protection - Vinyl Gloves

INTCO
英科医疗

Document Number : INTCO-CE-DC-PVC-001 Version: A/1

EU DECLARATION OF CONFORMITY

Manufacturer

Name: **Shandong Intco Medical Products Co., Ltd.**
Address: **Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China**

Authorized Representative

Name: **Lotus NL B.V.**

Address: **Koningin Julianaplein 10, le Verd, 2595AA, The Netherlands**

Declares that the MDR described hereafter

Product name and model:

Disposable Vinyl（PVC）Gloves

UMDNS code：11882

UDI-DI: 6970245751019 / 6970245751026 / 6970245751033 / 6970245751040 / 6970245751057

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

The medical device has been assigned to class **I** according to Annex *VIII* of the Regulation EU 2017/745. It bears the mark

CE

CONFORMITY ASSESSMENT ROUTE: *EU 2017/745, Annex I & VII*

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shandong Intco Medical Products Co., Ltd.
Address: Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

Shandong 2019-05-06 — *Place , date*

Chi Yongtao Plant manager — *Legally binding signature, Function*

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Vinyl Gloves

CMA
171021110579

检验检测报告
TEST REPORT

STFWT20200450

产品名称 Product Name	一次性 PVC 手套
委托单位 Trust Unit	山东英科医疗制品有限公司
生产单位 Manufacturer	山东英科医疗制品有限公司
检验检测类别 Test Category	委托送样检验

SPC 江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

SHIELD WORKS
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Hand Protection - Vinyl Gloves

检 验 检 测 报 告

Test Report

防伪查询

STFWT20200450

产品名称 Product Name	一次性 PVC 手套	规格型号 Specification Type	——
		商 标 Trademark	——
委托单位 Trust Unit	山东英科医疗制品有限公司	电 话 Tel	18266365220
生产单位 Manufacturer	山东英科医疗制品有限公司	样品等级 Sample Grade	——
样品数量 Sample Quantity	20 只	送样日期 Sample Receiving Date	2020-02-06
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	——
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	GB 15979-2002 《一次性使用卫生用品卫生标准》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合 GB 15979-2002 标准规定的要求。 签发日期：2020-02-14 SignatuimDate		
备 注 Remarks	本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。 本报告仅对来样负责。		

批 准：Approver 陈敏 审 核：Examiner 吴高高 主 检：Majortester 韦秀萍

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Vinyl Gloves

检 验 检 测 结 果
Testing Results

STFWT20200450

序号 Serial	检验检测项目 Test Items		单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	微生物指标	细菌菌落总数	CFU/g	≤200	16	合 格
		大肠菌群	——	不得检出	未检出	
		致病性化脓菌 金黄色葡萄球菌	——	不得检出	未检出	
		致病性化脓菌 绿脓杆菌	——	不得检出	未检出	
		致病性化脓菌 溶血性链球菌	——	不得检出	未检出	
		真菌菌落总数	CFU/g	≤100	8	

样 品 图 片

测试样品

以下空白

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Hand Protection - Vinyl Gloves

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SHIELD WORKS
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Hand Protection - Vinyl Gloves

Test Report No. 7191203047-EEC19-WBH
dated 28 Jan 2019

PSB Singapore

Add value.
Inspire trust.

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Disposable Vinyl Gloves (PVC) submitted by
Shandong Intco Medical Products Co., Ltd. on 16 Jan 2019.

TESTED FOR:

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

TEST DATE:

18 Jan 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Vinyl Glove (PVC)	Clear	/	M	200	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

SHIELD WORKS
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Hand Protection - Vinyl Gloves

Test Report No. 7191203047-EEC19-WBH
dated 28 Jan 2019

PSB Singapore

RESULTS:

Sample: Disposable Vinyl Gloves (PVC), 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	2	Passed

Yeo Poh Kwang
Higher Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo : Disposable Vinyl Gloves (PVC), Size M

Hand Protection - Vinyl Gloves

Test Report No. 7191203047-EEC19-WBH
dated 28 Jan 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.

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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

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Hand Protection - Vinyl Gloves

SGS

Test Report No.: QDHL1901001659OT Date: JAN.29,2019 Page: 1 of 4

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 VINYL GLOVE (PVC) COLOR: CLEAR
Sample Receiving Date	: JAN.16,2019
Testing Period	: JAN.16,2019 TO JAN.29,2019
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.
Approved by:

Zhou Xinkuan, SK
Lab Manager

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80991655
www.sgsgroup.com.cn
e sgs.china@sgs.com

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Vinyl Gloves

SGS

Test Report No.: QDHL1901001659OT Date: JAN.29,2019 Page: 2 of 4

Test Conducted:

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

Number of test sample	:	78 Pieces
The type of gloves	:	examination/procedure gloves c)
Manufacturing batch code	:	\
Size	:	Examination/procedure gloves: S, M, L, XL
Defects observed before testing	:	No defects

Clause	Test Items	Result	Note
4	Dimensions	---	---
4.2	Length	Pass	# 1
4.3	Width	Pass	# 1
5	Strength	---	---
5.2	Force at break	Pass	# 2
5.3	Force at break after challenge testing	Pass	# 2

Notes : #1 See result 1
#2 See result 2

Test Result:

1. Dimensions

Sample Quantity: 4 x 13 pcs

Size	S												
Length(mm)	246	244	244	245	246	248	245	245	247	248	244	249	245
Width(mm)	86	88	89	89	87	89	89	88	89	88	88	88	88

Size	M												
Length(mm)	250	240	243	244	246	245	242	251	241	245	256	245	249
Width(mm)	96	98	98	97	97	98	99	98	96	98	96	98	96

Size	L												
Length(mm)	254	250	251	250	248	259	245	254	252	250	250	248	256
Width(mm)	107	105	108	107	106	106	106	107	106	106	107	106	105

Size	XL												
Length(mm)	252	251	251	254	243	249	249	254	248	251	249	248	250
Width(mm)	114	114	115	115	114	115	114	116	116	115	115	115	115

Median value:
S, Length (mm): 245 Width (mm): 88
M, Length (mm): 245 Width (mm): 98
L, Length (mm): 250 Width (mm): 106
XL, Length (mm): 250 Width (mm): 115

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80981655
www.sgsgroup.com.cn
e sgs.china@sgs.com

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Vinyl Gloves

SGS

Requirements: see table 1&2

Table 1 Dimensions for surgical gloves

Size	Median length in mm	Median width in mm
5	≥250	67±4
5.5	≥250	72±4
6	≥260	77±5
6.5	≥260	83±5
7	≥270	89±5
7.5	≥270	95±5
8	≥270	102±6
8.5	≥280	108±6
9	≥280	114±6
9.5	≥280	121±6

Table 2 Dimensions for examination/procedure gloves

Size	Median length in mm	Median width in mm
Extra small	≥240	≤80
Small		80±10
Medium		95±10
Large		110±10
Extra Large		≥110

2. Strength

Sample Quantity: 26pcs

Size	M												
Force at break(N)	4.7	4.6	4.5	4.1	4.4	4.2	4.6	4.1	4.2	4.6	4.5	4.2	4.3
Force at break after challenge testing(N)	4.1	4.8	5.1	4.5	4.9	4.8	4.0	5.1	4.6	4.3	4.4	4.9	4.6

Median value:

Force at break during shelf life (N): 4.4

Force at break after challenge testing (N): 4.6

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).

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Hand Protection - Vinyl Gloves

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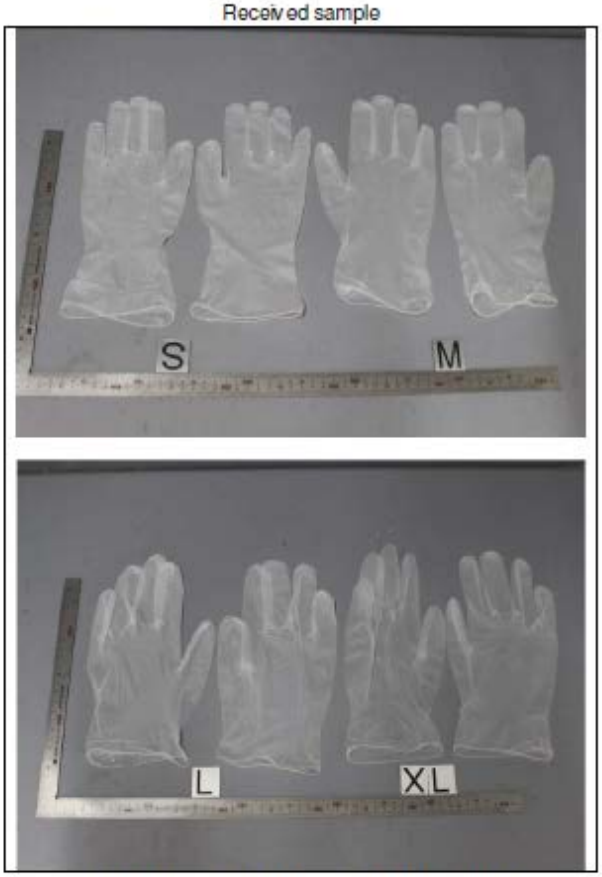
Test Report No.: QDHL1901001659OT Date: JAN.29,2019 Page: 4 of 4

Sample Photo:

Received sample



SGS authenticate the photo on original report only

End of Report

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SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Vinyl Gloves

Instruction Manual

[General name] Disposable Vinyl gloves

[Size & Standard] Size: XS, X, M, L, XL. Standard: 10 pcs/box, 12 pcs/box, 20 pcs/box, 50 pcs/box, 60 pcs/box, 80 pcs/box, 100 pcs/box

[Manufacturer] SHANDONG INTCOMEDICAL PRODUCTS CO.LTD

[Contact] Qiwang Road, Naoshan Industrial Park, Qingzhou, Shandong, China, 262500,
0536 - 6136888

[Structure composition & Description] For patient examination.
Made of Vinyl. For single-use only. Non-sterile gloves.

[Range of application] For medical and nursing staff, typically used for examination and to prevent cross-infection between doctors and patients.

[Notes]
1. For adults only;
2. To be used in 10^{o}C - 30^{o}C.
3. Before using, please trim your fingernails to avoid any damage.
4. Don’t wear any accessories when using the gloves.
5. One-time using and can not be reused.
6. Please do not use if the package is damaged.
7. After using, Dispose of the product as bio-hazardous waste per institutional protocol.

[Contraindications]
1. If you have any discomfort, please stop using it immediately.
2. Please keep away from corrosive chemical such as acid-base and organic solvent, to avoid any damage.

[Instructions] Open the box, and take the gloves out of packaging and wear

[Storage] Store in a cool dry place, relative humidity ≤ 80%, avoid direct sunlight.
[Date of manufacture] Refer to product box
[Validity period] 5 years

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Vinyl Gloves

TEMPERATURE LIMITATION:
10°C - 30°C

SINGLE-USE

KEEP AWAY FROM SUNLIGHT

KEEP AWAY FROM RAIN

RECYCLABLE

DISPOSE IMMEDIATELY AFTER USE

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Vinyl Gloves

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：鲁潍食药监械出 20160020
Certificate NO.: Approved by Shandong Weifang food drug safety system20160020

产品名称：一次性丁腈检查手套 | 一次性乳胶检查手套 | 一次性 PVC 检查手套
Product(s): Disposable nitrile examination gloves | Disposable latex examination gloves | Disposable vinyl examination glove

规格型号：XS 、S、 M、 L、 XL | XS 、S、 M、 L、 XL | XS 、S、 M、 L、 XL
Model: XS 、S、 M、 L、 XL | XS 、S、 M、 L、 XL | XS 、S、 M、 L、 XL

产品注册或备案凭证号：鲁潍械备 20160022 号 | 鲁潍械备 20160023 号 | 鲁潍械备 20160024 号
Registration certificate(s): Shandong Weifang feed system of drug safety SIUP 20160022 | Shandong Weifang feed system of drug safety SIUP 20160023 | Shandong Weifang feed system of drug safety SIUP 20160024

生产企业：山东英科医疗制品有限公司
Manufacturer: Shandong Intco Medical Prodncts Co.,Ltd

生产企业住所：山东省青州市猛山经济开发区齐王路 9888 号
Address of manufacturer: No.9888,Qiwang Road, Naoshan economic development area, Qingzhou, Shandong Province

生产许可或备案凭证号：鲁潍食药监械生产备 20160008 号
Manufacturing License(s): Record by Shandong(Lu) Weifang(Wei) drug safety food machinery 20160008

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2018 年 10 月 17 日
This certification valid until:

备注：
Remark:

2016 年 10 月 18 日

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection

营业执照

（副本）

统一社会信用代码 91370781561439654L 1-1

名　　称 山东英科医疗制品有限公司

类　　型 其他有限责任公司

住　　所 青州市猛山工业园齐王路

法定代表人 刘方毅

注册资本 肆亿零陆佰万元整

成立日期 2010年08月23日

营业期限 2010年08月23日至2030年08月23日

经营范围 丁腈手套、PVC手套生产销售，PE手套、乳胶手套、PVC粉、橡胶制品、塑胶制品、化工产品、煤炭销售，货物进出口（依法须经批准的项目，经相关部门批准后方可开展经营活动）。

登记机关

2018 年 01 月 02 日

提示：1. 每年1月1日至6月30日通过企业信用信息公示系统报送并公示上一年度年度报告，不另行通知；
2.《企业信息公示暂行条例》第十条规定的企业有关信息形成后20个工作日内需要向社会公示（个体工商户、农民专业合作社除外）。

企业信用信息公示系统网址：http://sd.gsxt.gov.cn

中华人民共和国国家工商行政管理总局监制

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection

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Certificate CN13/10046

The management system of

Shandong Intco Medical Products Co., Ltd.

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

Unified Social Credit Code 91370781561439654L

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

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

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

This certificate is valid from 10 April 2017 until 15 September 2018
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 4. Certified since 27 January 2013

Authorised by

SYSTEM CERTIFICATION
ISO 9001
SGS

UKAS
MANAGEMENT
SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

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SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection

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Certificate CN14/10163

SYSTEM CERTIFICATION ISO 13485 SGS

The management system of

Shandong Intco Medical Products Co., Ltd.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

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

Effective Date 10 April 2017 Expiry Date 31 December 2018
Re certification audit due before 8 December 2018
Valid subject to satisfactory surveillance audits.
Issue 4. Certified since 28 April 2014

Authorised by
Jan Saunders – Business Manager

SCC Accredited CB-MS OCSM Accrédité CCN TM

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Page 1 of 1

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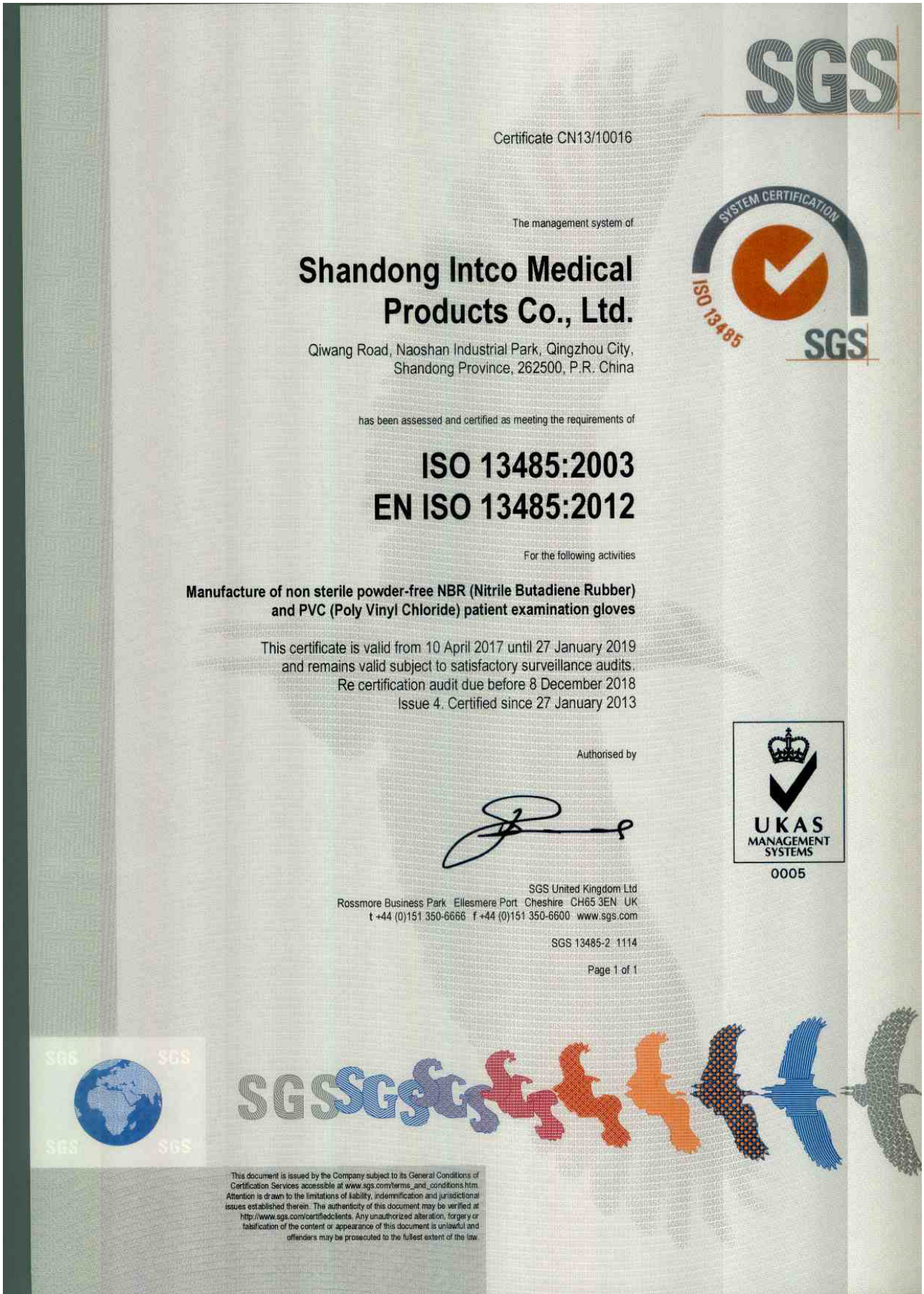
SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection



SGS

Certificate CN13/10016

SYSTEM CERTIFICATION ISO 13485 SGS

The management system of

Shandong Intco Medical Products Co., Ltd.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2003
EN ISO 13485:2012

For the following activities

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

This certificate is valid from 10 April 2017 until 27 January 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 8 December 2018
Issue 4. Certified since 27 January 2013

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

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Page 1 of 1

SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Document Number: SWPPE-CE-NIGLV-001 Version: 001

EC DECLARATION OF CONFORMITY

Manufacturer

Name: **SHANDONG INTCO MEDICAL PRODUCTS CO. LTD**

Address: **Qiwang Road, Naoshan Industrial Park, Qingzhou, Shandong, China**

Authorized Representative

Name: **China 2 West Services Limited**

Address: **Flat /RM 16E, Neich Tower, 128 Gloucester Rd, Wanchai, HongKong**

Declares that the MDD described hereafter

Product name and model:

Disposable Vinyl Gloves Powdered and Powder free, Non-Sterile

The product is certified to meet the Essential requirements and relevant provisions of

Annex II of the PPE Regulation EU 2016/425 as a Category III product.

Standard(s)/Directive(s):
EN 455-1:2000
EN 455-2-2015
EN 420:2003+A1:2009
EN 388:2016
EN ISO 374-1:2016/Type B
EN ISO 374-5:2016

as shown in the CE Certificate and test report:

2777/11030-03/E00-00 **7191203047-EEC19-WBH**

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above-mentioned declaration of conformity is exclusively under the responsibility of

Company: China 2 West Services Limited
Address Flat /RM 16E, Neich Tower, 128 Gloucester Rd, Wanchai, HongKong

Zhuhai China, 2020-04-29
Place, date

Expiry date: 2021-04-29

CHINA 2 WEST SERVICES LIMITED

Mark Clayton, Group CFO
Legally binding signature

shieldworksppe.com

Get in touch

For serious inquiries, contact us for more information and an accurate quote.

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info@shieldworksppe.com
China Headquarters: +86 (0)756 3828390
US Head Office: (+1) 650 666 0050

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SHIELD WORKS
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