



COVID-19 PPE & Medical Equipment

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Hand Protection - Nitrile Gloves



SHIELD WORKS

QUALITY PROTECTION EQUIPMENT

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Shield Works PPE

With 15 years of China manufacturing experience and a team of over 50 project managers and engineers, we have the infrastructure and knowledge to ensure that all medical products are supplied by approved manufacturers to required national standards. This eliminates the risk of bulk shipments being impounded by customs at port of entry.

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Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K110981
Device Name	POWDER-FREE NITRILE PATIENT EXAMINATION GLOVES
Applicant	SHANDONG YINGHONG MEDICAL PRODUCTS CO., LTD. 12390 EAST END AVE. Chino, CA 91710
Applicant Contact	Frank Liu
Correspondent	SHANDONG YINGHONG MEDICAL PRODUCTS CO., LTD. 12390 EAST END AVE. Chino, CA 91710
Correspondent Contact	Frank Liu
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	04/07/2011
Decision Date	07/12/2011
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Page Last Updated: 05/11/2020
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Hand Protection - Nitrile Gloves



Issued to:

Shandong IntooMedical 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: 2777/11804-01/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: 697024575
Description: Five fingered disposable nitrile non-sterile gloves.

Blue 697024575 601-605

Violet 697024575 631-635

White 697024575 641-645

Black 697024575 651-655

Sizes:

6/XS, 6.5/S, 7/M, 8/L, 9/XL

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	Level	EN 374-4: 2013
40% Sodium Hydroxide (K)	6	-11.5 %
30% Hydrogen peroxide (P)	2	-9.5%
37% Formaldehyde (T)	3	7.4 %
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 ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: CHT0278438/1848

SGS: QDHL18080131130T, CH:TX:6420074520, CH:TX: 9420020333, CH:TX: 9420029243 CH:TX: 9420026599-1, CH:TX:

9420014953-1, CH:TX: 9420026316-1, CH:TX: 9420614959

TUV: 721642857-2

Signed on behalf of SATRA:

Tara Saunders

Geoff Graham

Date first issued: 30/01/2019

Date of issue: 30/01/2019

Expiry date: 30/01/2024



Hand Protection - Nitrile 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 certification and product 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. 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.
8. 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.
9. SATRA Technology 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
QUALITY PROTECTION EQUIPMENT

Hand Protection - Nitrile Gloves



Document Number : INTCO-CE-DC-NBR-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

Declares that the MDR described hereafter

Product name and model:

Disposable Nitrile (NBR) Gloves

UMDNS code: 11882

UDI-DI: (XS, S, M, L, XL, XXL)

Blue Gloves: 6970245756014 / 6970245756021 / 6970245756038 / 6970245756045 / 6970245756052 / 6970245756069

White Gloves: 6970245756410 / 6970245756427 / 6970245756434 / 6970245756441 / 6970245756458 / 6970245756465

Black Gloves: 6970245756519 / 6970245756526 / 6970245756533 / 6970245756540 / 6970245756557 / 6970245756564

Violet Gloves: 6970245756311 / 6970245756328 / 6970245756335 / 6970245756342 / 6970245756359 / 6970245756366

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



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 - Nitrile Gloves

Certificate GB16/871585

Shandong Intco Medical Products Co., Ltd.

No.9888 Qiwang Road,
Naoshan Industrial Park,
Qingzhou,
Shangdong,
262500 China.

It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

EC Directive 89/686/EEC

EC Type-examination

This certificate is valid from 12 May 2016 until 21 April 2023
Issue 1. Certified since 12 May 2016

Authorised by

SGS United Kingdom Limited, Notified Body 0120

Unit 202B Worle Parkway, Weston-super-Mare, BS22 6WA, United Kingdom
t +44 (0)1934 522917f +44 (0)1934 522137
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SGS EC 03 1011

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QUALITY PROTECTION EQUIPMENT

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Certificate GB16/871585, continued

Shandong Intco Medical Products Co., Ltd.

EC Directive 89/686/EEC

EC Type-examination

Issue 1

PPE Product

Synguard (logo) disposable nitrile gloves, ambidextrous NBR disposable gloves with a nominal palm thickness of 0.08mm, which are available in two colour options: Blue & White, and five nominal hand sizes: XS, S, M, L & XL.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to be in accordance with the requirements of Council Directive 89/686/EEC. When examined the PPE satisfied the requirements in the relevant harmonized standard:

EN 374-1:2003 (Protective gloves against chemicals and micro-organisms) including clause 5.2 with EN 374-2:2003 inspection level 2, but excluding the minimum requirements for clause 5.3.2 (EN 374-3:2003 permeation (\geq level 2) with three reagents from the list in Annex A of EN 374-1:2003).

The manufacturer's information notice [INTCO-TF appendix D instructions for use], in English, has been inspected and found to have addressed all of the relevant requirements of the standard. However, the detailed content of the information notice is the responsibility of the manufacturer, as are translations into other languages.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 11 of the Directive are implemented and maintained while the model is in production.

Certification is based on technical file specification: INTCO-TF, Rev A1 dated 2016-2-15.

SGS Reference Number GB/PP 234995

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Hand Protection - Nitrile Gloves



Test Report No.: SHHL1703010719MD-01 Date: MAR. 28, 2017 Page: 1 of 5

QINGDAO HARDLINES LAB

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1703010719MD
DATE: MAR. 22, 2017

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

Sample Description : BLUE NITRILE EXAMINATION GLOVES
 SGS Ref. No. : QDHL17030042090T
 LOT No. : 5516-20170104
 Sample Receiving Date : MAR. 13, 2017
 Testing Period : MAR. 13, 2017 TO MAR. 22, 2017
 Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
 Test Requested : 1. FREEDOM FROM HOLES (ASTM D6319-10 CLAUSE 6.1.2)
 2. PHYSICAL DIMENSIONS (ASTM D6319-10 CLAUSE 6.1.3)
 3. PHYSICAL PROPERTY CHARACTERISTICS (ASTM D6319-10 CLAUSE 6.1.4)
 4. POWDER RESIDUE FOR POWDER FREE GLOVES (ASTM D6319-10 CLAUSE 6.1.5)

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.

Melody Zhang
Authorized Signatory



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Hand Protection - Nitrile Gloves



Test Report No.: SHHL1703010719MD-01 Date: MAR. 28, 2017 Page: 2 of 5

Test Conducted:

ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application

Number of test sample : 244 pcs
Accelerated aging condition : 70 °C, 166 h
Defects observed before testing : No defect
Test Result : Pass

Clause	Test Items	Result	Note
6.1.2	Freedom from Holes	Pass	#1
6.1.3	Physical dimensions	Pass	#2
6.1.4	Physical property characteristics	Pass	#3
6.1.5	Powder Residue For Powder Free Gloves	Pass	#4

- Notes :
- # 1- Test details see test result 1.
 - # 2- Test details see test result 2.
 - # 3- Test details see test result 3.
 - # 4- Test details see test result 4.
 - # 5- The sample selecting amount for Freedom from Holes is deviated to 200 pcs as accessed by SGS.
 - # 6- The sample selecting amount for Physical dimensions and Physical property characteristics is deviated to 13 pcs per test as accessed by SGS.
 - # 7- The hardness of the glove is materials < 35 IRHD as per client's claim.



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Hand Protection - Nitrile Gloves



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Test Result:

1. Freedom from Holes

Sample Quantity: 200

AQL: 2.5 Accept: 10 Reject: 11 Found: 0

2. Dimensions

Sample Quantity: 13

AQL: 4.0 Accept: 1 Reject: 2 Found: 0

Size	Sample No.	Length mm	Width mm	Thickness at finger mm	Thickness at palm mm
M	1	245	95	0.094	0.059
	2	246	95	0.099	0.062
	3	235	95	0.103	0.059
	4	243	95	0.096	0.058
	5	240	95	0.106	0.062
	6	242	95	0.093	0.060
	7	245	98	0.103	0.061
	8	246	96	0.094	0.058
	9	245	95	0.100	0.059
	10	243	94	0.093	0.056
	11	243	95	0.086	0.056
	12	245	94	0.089	0.063
	13	243	95	0.091	0.060
	Found	0	0	0	0

Requirements: see table 1

Table 1 Dimensions and tolerances

NOTE: Sizing that falls within the tolerance overlaps between two sizes may be labeled as a size range including both sizes, for example, small/medium and medium/large.

Designation	Size							Tolerance, mm	
	6	6½	7	7½	8	8½	9		
Width by size, mm	75	83	89	95	102	108	114	±6	
Width by	x-small	small	unsize	medium	large	X-Large			
		70	80	85	95	110	120	±10	
Length, mm		220	220	230	230	230	230	Min.	
Thickness, mm									
Finger								0.05	Min.
Palm								0.05	Min.



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3. Tensile Properties

Sample Quantity: 26

AQL: 4.0 Accept: 1 Reject: 2 Found: 0

Sample No.	Before ageing		After ageing	
	Tensile strength MPa	Ultimate Elongation %	Tensile strength MPa	Ultimate Elongation %
1	21.6	856.7	27.3	793.3
2	31.3	746.7	31.6	833.3
3	34.6	749.6	23.2	706.7
4	31.7	1023.3	32.2	893.3
5	29.3	996.7	24.8	680.0
6	23.3	916.7	29.9	810.0
7	21.9	952.5	28.1	806.7
8	30.4	1016.7	29.5	806.7
9	29.5	1040.0	32.7	856.7
10	34.1	1058.8	34.3	1023.3
11	28.3	1030.0	30.1	853.3
12	17.1	826.7	26.1	846.7
13	25.5	976.6	32.3	980.0
Found	0	0	0	0

Requirements: see table 1

Table 1- Physical requirements

Before aging		After aging	
Tensile strength	Ultimate Elongation	Tensile strength	Ultimate Elongation
14 MPa Min.	500% Min.	14 MPa Min.	400% Min.

4. Powder Residue for Powder Free Gloves

Test Item	Test Method	Requirement	Test result	Rating
Powder residue	Clause 7.6	Have a powder residue limit of 2.0 mg.	0.46	Pass



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Hand Protection - Nitrile Gloves



Test Report

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Date: MAR. 28, 2017

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Sample Photo:

Sample as received (Size M)



SGS authenticate the photo on original report only

End of Report



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Hand Protection - Nitrile Gloves



Analysis Report **SHAHG1926089102A01** Date: Dec. 5, 2019 Page 1 of 6

SHANDONG INTOCO 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

Helen Liu
Approved Signatory



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Hand Protection - Nitrile Gloves



Analysis Report

SHAHG1926089102A01 Date: Dec. 5, 2019

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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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Hand Protection - Nitrile Gloves



Analysis Report

SHAHG1926089102A01

Date: Dec. 5, 2019

Page 3 of 6

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($\mu\text{g}/\text{ml}$)	Not detected

Remark:

- 1: $\mu\text{g}/\text{ml}$ = microgram per milliliter
- 2: Detection limit of aqueous extractable protein is 2 $\mu\text{g}/\text{ml}$

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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Testing Center, China

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Hand Protection - Nitrile Gloves



Analysis Report

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Date: Dec. 5, 2019

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Representative attachments

1: FTIR

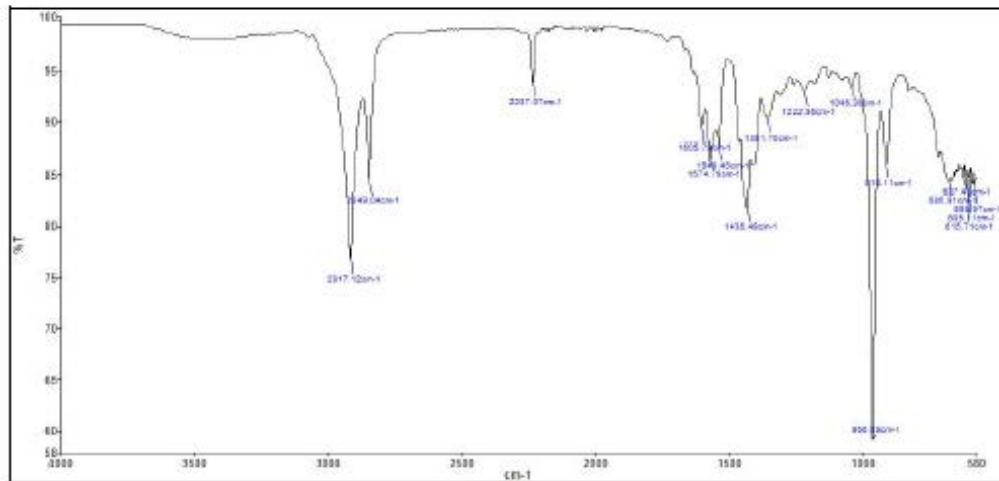


Fig.1



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Hand Protection - Nitrile Gloves



Analysis Report **SHAHG1926089102A01** Date: Dec. 5, 2019 Page 5 of 6

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Hand Protection - Nitrile Gloves



Analysis Report

SHAHG1926089102A01 Date: Dec. 5, 2019

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Sample photo:



SGS authenticate the photo on original report only

*** End of Report ***



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SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Nitrile Gloves

Instruction Manual

[General name] Disposable Nitrile 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 Nitrile. 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^oC - 30^oC.
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 - Nitrile 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 - Nitrile 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 system 20160020

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 Products Co., Ltd

生产企业住所：山东省青州市峒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:





SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Nitrile Gloves

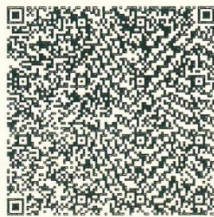


营业执照

(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 青州市刁山工业园齐王路
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)。



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2018年01月02日

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SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Nitrile Gloves



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

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
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SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Nitrile Gloves



Certificate CN14/10163

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

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Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
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SHIELD WORKS
QUALITY PROTECTION EQUIPMENT

Hand Protection - Nitrile Gloves



Certificate CN13/10016

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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

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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:

Five fingered disposable nitrile non-sterile gloves.

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

EC Directive: 89/686/EEC

Standard(s)/Directive(s):

EN 374-1:2003
EN 374-2:2003
EN ISO 374-1:2016+A1:2018/Type B
EN ISO 374-5:2016

as shown in the CE Certificate:

2777/11804-01/E00-00

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



Mark Clayton, Group CFO
Legally binding signature

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