

Nitril Schutzhandschuhe

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Prävention-mit-Kopf GmbH

DE- Grafenberger Allee 277-287 40237 Düsseldorf HRB 27734- Amtsgericht Koblenz Rechtsform: Gesellschaft m.b.H

Commerzbank

IBAN: DE73570400440204493100 **BIC: COBADEFFXXX**

USt.-IdNr. DE337526020

100 bcs px weight

SINGLE USE JARA-KATAJ POWDER-FREE NON-STERILE

> (BY WEIGHT) TOO bee

S3VOJS 3JIATIN

NITRILE GLOVES

100 PCS (BY WEIGHT)

M

100 pcs by weight

NON-STERILE POWDER-FREE LATEX-FREE SINGLE USE



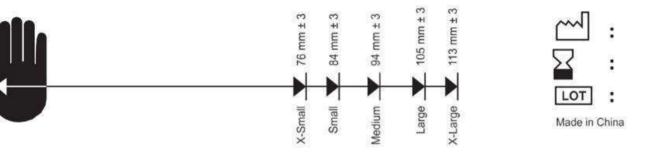


(BY WEIGHT)

nformation:

nponents used in making these gloves may cause allergic reactions in some individuals. Do not expose these gloves to ar th a known or suspected sensitivity to any components used in the manufacture of these gloves before consulting a . If allergic reactions occur, discontinue use immediately and consult with a physician.

dry place at room temperature. Open product should be shielded from exposure to direct sunlight, intense artificial y machines, and other sources of ozone.























EN 374



Certificate

ICR Polska/CE/V/P6402033

DONGTAI CITY HUAYI GLOVES CO., LTD

36 Nanzhuang Road, High-tech Industrial Development zone of Dongtai City,

Jiangsu Province, 224249 P.R. China

DONGTAI CITY HUAYI GLOVES CO., LTD

36 Nanzhuang Road, High-tech Industrial Development zone of Dongtai City,

Jiangsu Province, 224249 P.R. China

Product nam e:

Disposable Gloves

Product types:

\$20006, \$20003, \$20007, \$20008, \$20009, \$20010, \$20010, \$20013

Product tradem ark:

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2014

The certification process has been carried out in accordance with the program PC-P-07-07

Evaluation has been carried out in accordance with test reports made by

East Verify Certification Service Co., Ltd.

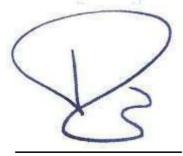
EVC2004154GZ94E1 No. of test reports:

08.04.2020 Certificate issue date: 07.04.2025 Expiration date:

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3109.

This certificate applies to products having the same attributes (parameters), intended use, that hav $\label{eq:continuous} \textbf{n} \ \ \textbf{evaluated} \ \ \textbf{and} \ \ \textbf{m} \ \ \textbf{eet} \ \ \textbf{the} \ \ \textbf{requirements} \ \ \textbf{of} \ \ \textbf{the} \ \ \textbf{aforementioned} \ \ \textbf{standard} \ .$





Director: Rafał Kalinowski

Warsaw, 08.04.2020





东台市华亿手套有限公司

一次性丁腈手套(Nitrile Gloves)



公司: 东台市华亿手套有限公司

地址: 江苏省东台市 销售办事处: 江苏省张家港市

产品名称:一次性丁腈手套(蓝色、无粉)

已获认证: FDA, CE, ISO9001(TUV), ISO13485(TUV), PPE(SATRA)

日产量: 200 万只

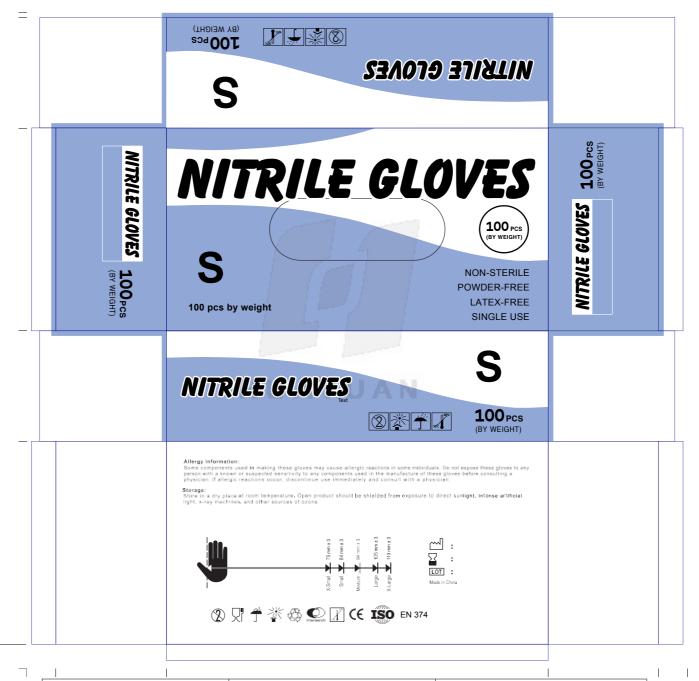


1. 产品实物:





2. 包装图片



☑号 (Item):100只中性包装盒☑色	尺寸 (size):243 x 133 x 54 mm	材料 (material):
色号 (pantoneno):		図注 (remark):



3. 尺寸重量

一次性丁腈手套(蓝色、无粉、非灭菌)

包装方式: 100 只/盒, 10 盒/箱 (=1,000 只/箱)

内盒尺寸: 243x133x54mm

外箱尺寸: 285×280×260mm

装柜数量:

1300ctns/20ft container

2800ctns/40ft container

3200ctns/40HQ container

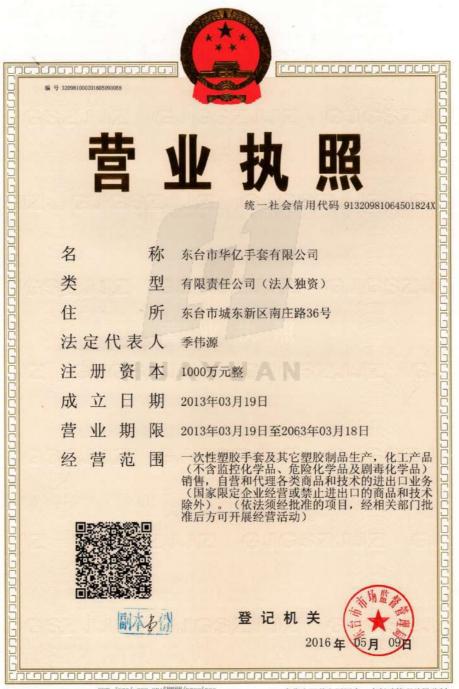
毛净重参考(以 M 号 5 克为例):

N. W. : $S/M/L/XL \approx 4.7 kg/5.0 kg/5.3 kg/5.7 kg$

G. W. : $S/M/L/XL \approx 5.7kg/6.0kg/6.3kg/6.7kg$



4. 营业执照

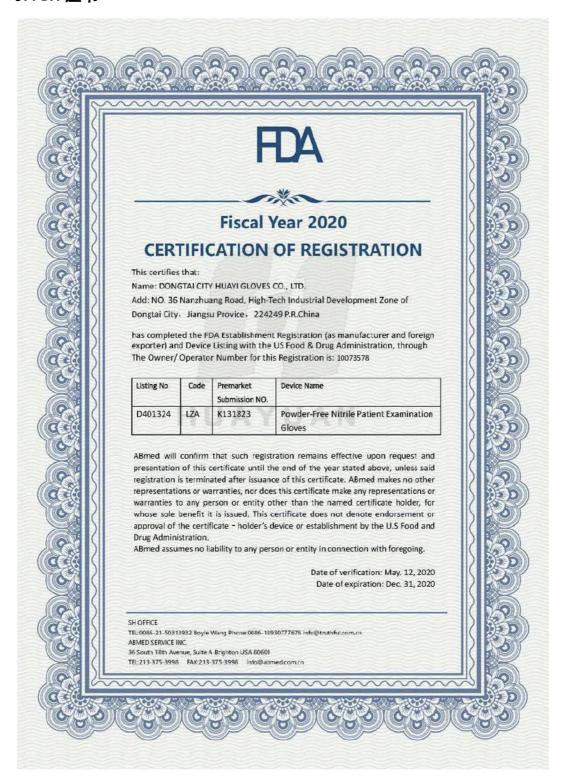


企业信用信息公示系统网址: www.jsgsj.gov.cn:58888/province

中华人民共和国国家工商行政管理总局监制



5. FDA 证书





6. IS09001 证书 (TUV)

CERTIFICAT THE SUB TENSOR THE SUB-THE SUB-CEPTUФUKAT ◆ CERTIFICADO ◆ • . CERTIFICATE ZERTIFIKAT +



CERTIFICATE

The Certification Body of TÜV SÜD Management Service GmbH certifies that

Dongtai City Huayi Gloves Co., Ltd.
No. 36 Nanzhuang Road, East New District
Dongtai City, Jiangsu, P.R. China
Post Code: 224200

Unified social credit code: 91320981064501824X

has established and applies a Quality Management System for

Production and Distribution of Nitrile Examination Gloves.

An audit was performed, Order No. 7482274766. Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from 2020-04-11 until 2023-04-10.

The certified organization shall undergo and pass the regular surveillance audit to maintain the validity of this certificate.

Certificate Registration No.: 12 100 47761 TMS.

Information about this certificate can be incuired at the official website of Certification and Accreditation Administration of the People's Republic of China (www.cnza.gov.cn)





TÜV SÜD Management Service GmbH • Zertifizierungsstalle • Ridlerstraße 65 • 80339 München • Germany



7. ISO13485 证书 (TUV)





8. EN455 检测报告(SGS)

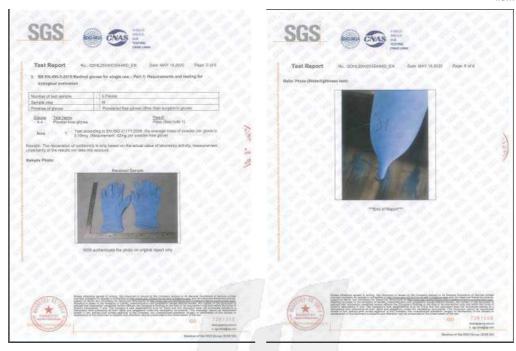












9. **GB4806**. **11–2016** (SGS)











10. 产品参数

		1		
	Specifications	ASTM D6319		
	≥240	XS\S	XS\S≥220, M/L/XL≥230	
XS	1	XS	70 ± 10	
S	85±5	S	80±10	
M	96±5	M	95±10	
L	108±5	L	110±10	
XL	115±5	XL	120±10	
Finger	0.24 ± 0.03 mm	Finger	≥0.10	
Palm	0.20±0.03mm	Palm	≥0.10	
Cuff	0.17±0.03mm	Cuff	N/A	
XS	/	XS	N/A	
S		S	N/A	
M	5.0±0.3	M	N/A	
L		L	N/A	
XL		XL	N/A	
Before Aging	≥14	Before Aging	≥14	
After Aging	≥14	After Aging	≥14	
Before Aging	≥500	Before Aging	≥500	
After Aging	≥400	After Aging	≥400	
€2.0			€2.0	
N/A			N/A	
	S M L XL Finger Palm Cuff XS S M L XL Before Aging After Aging Before Aging	XS	XS	



11. 第一类医疗器械备案凭证

第一类医疗器械备案凭证

东台市华亿手套有限公司:

根据相关法规要求,对你单位第一类医疗器械:一次性使用 医用丁腈橡胶检查手套予以各案,备案号: 苏盐械备 20140001 号

> 盐城市食品药监督管理局 日期・つい以 年 a8月 oで日

产品合格证

Product Certification

产品名称: 丁腈手套(非医用)

规格型号:

见外包装 Specification

产品成分: 丁腈胶乳 Product Composition

20201005

Lot No.

生产日期: 2020-10

MFG Date

五年 有效期:

执行标准:

Executive Standard

检验员:

Inspector No.

东台市华亿手套有限公司

地址: 江苏省东台市城东新区南庄路36号



CUSTOMER NAME:

TEST REPORT

No.: SHIN2010066861MR

Date: Oct 23, 2020

Page: 1 of 6

QH HEALTHCARE – COST CAPITAL GROUP

ADDRESS: 23 RUSHCROFT ROAD,LONDON,ENGLAND E4 8SG

Sample Name : DISPOSABLE NITRILE GLOVES

Buyer : QH HEALTHCARE - COST CAPITAL GROUP

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 Ref. No. : SHIN2010065020PS

Date of Receipt : Oct 20, 2020
Testing Start Date : Oct 20, 2020
Testing End Date : Oct 23, 2020

Test result(s) : For further details, please refer to the following page(s)

(Unless otherwise stated the results shown in this test report refer only to

the sample(s) tested)

Signed for SGS-CSTC Standards Technical Service (Shanghai)Co., Ltd.

(rable

Xia Hai

Authorized signatory





No.: SHIN2010066861MR

Date: Oct 23, 2020

Page: 2 of 6

Summary of Results:

No.	Test Item	Test Method	Result	Conclusion
1	Total thickness	Provided by client	0.123 mm	1
2	Major Composition Qualitative Analysis	ASTM D3677-10(2019)	Acrylonitrile- butadiene rubber	1
3	Weight	Provided by client	3.82 g	1

Note: Pass: Meet the requirements;

Fail: Does not meet the requirements;

/: Not Apply to the judgment.





No.: SHIN2010066861MR

Date: Oct 23, 2020

Page: 3 of 6

1. Test Item: Total thickness

Sample Description: Rubber specimen

Test Method: Provided by client

Test Condition:

Diameter of Presser foot: 10 mm

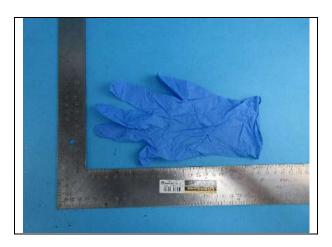
Load: 82 g

Lab Environmental Condition: 23 \pm 2 $^{\circ}$ C, 50 \pm 5 $^{\circ}$ RH

Test Result:

Test Item	Test Result	
Total thickness	0.123 mm	

Original Sample Photo:







No.: SHIN2010066861MR

Date: Oct 23, 2020

Page: 4 of 6

2. Test Item: Major Composition Qualitative Analysis

Sample Description: Rubber specimen

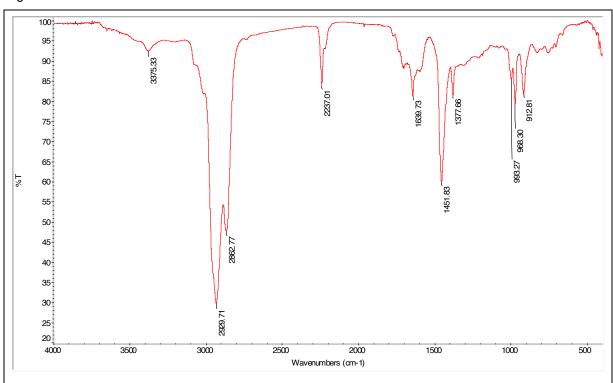
Test Method: ASTM D3677-10(2019), analysis was performed by FTIR.

Sample Technique: Pyrolyzate capillary film

Test Result:

Sample	Major composition	
Rubber specimen	Acrylonitrile-butadiene rubber (FTIR spectrum see Fig.1)	
	(FTIR spectrum see Fig	

Fig.1





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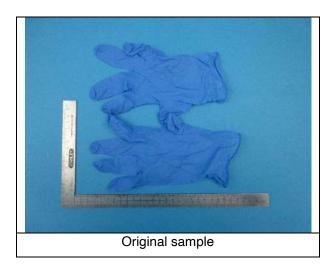


No.: SHIN2010066861MR

Date: Oct 23, 2020

Page: 5 of 6

Test Photo:







No.: SHIN2010066861MR

Date: Oct 23, 2020

Page: 6 of 6

3. Test Item: Weight

Sample Description: Rubber specimen

Test Method: Provided by client

Test Condition:

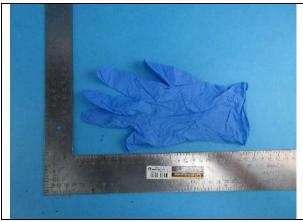
Measuring tool: Electronic balance

Lab Environmental Condition: 23 \pm 2 $^{\circ}$ C, 50 \pm 5 $^{\circ}$ RH

Test Result:

Test Item	Test Result	
Weight	3.82 g	

Original Sample Photo:



****** End of report******







No.: QDHL2004003544MD_EN

Date: MAY.18,2020

Page: 1 of 6

Client name : DONG TAI CITY HUAYI GLOVES CO.,LTD

Client address : NO.36 NANZHUANG ROAD, EAST NEW DISTRICT, 224200

DONGTAI CITY, JIANGSU, PEOPLE'S REPUBLIC OF CHINA

Sample Description : DISPOSABLE NITRILE GLOVES

Lot No. : NOT PROVIDED

Lot Size : NOT PROVIDED

Sample Quantity : 360PCS

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

Sample Receiving Date : APR.29,2020

Test Performing Date : APR.29,2020 TO MAY.18,2020



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QD

7361591







Test Report No.: QDHL2004003544MD_EN Date: MAY.18,2020 Page: 2 of 6

Test Requested Result

1. BS EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE – PART 1:

REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES (CLAUSE 5.1)

2. BS EN 455-2:2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: Pass REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES (CLAUSE 4.2,

4.3, 5.2, 5.3)

3. BS EN 455-3:2015 MEDICAL GLOVES FOR SINGLE USE—PART 3: Pass REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION (CLAUSE

Remark: - Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

Jessia Goo

scan to see the report

Jessica Gao Approved Signatory



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7361592





No.: QDHL2004003544MD EN

Date: MAY.18,2020

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BS EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

Number of test sample	:	200 Pieces
Sample size	:	M SY E CO SY E CO
Number of non-conforming gloves	:	1pc

Clause Test Items Result Watertightness test for detection of holes 5.1 Pass (See note 1) Referee testing

Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:1. See refer photo.

The sample selecting amount for this clause is deviated to 200 pcs as assessed Note

by SGS.

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

Number of test sample	201	26 Pieces
Туре		examination/procedure gloves b)
Size	- 7	Examination/procedure gloves: M

Clause	Test Items	Result
4	Dimensions	
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength	- 69-12 P
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)



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Date: MAY.18,2020

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Result 1: Dimensions

Size	N	N _G _G
No.	Length (mm)	Width (mm)
- 1 - 60 - 3	240	96
2	241	96
3	246	97
4	246	96
5	245	97
6	240	97
2 7 7 2	244	96
8	241	97
9	241	96
10	245	96
c 11 2 c	245	96
12	247	96
13	243	95
Standard requirement	≥240	95±10
Median value	244	96

Result 2: Strength

3 600	.CCS	Size: M	
, , ,55	Ford	ce at break (N)	-GP - GP
Befor	re aging	Afte	er aging
No.	1	No.	
1	16.5	0 6 100 8	16.3
2	17.1	2	16.0
3	15.0	3 3	16.2
4	16.9	9 4 4	14.7
5	18.2	5	17.7
6	15.1	6	16.5
7	17.0	7	16.7
8	16.7	8	17.1
9	12.1	9	12.2
10	15.6	10	14.8
11	13.4		12.2
12	17.2	12	14.6
13	13.0	13	15.7
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	16.5	Median value	16.0



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Date: MAY.18,2020

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 BS EN 455-3:2015 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation

Number of test sample		5 Pieces
Sample size		M
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves

Clause

Test Items

Powder-free gloves

Result

Pass (See note 1)

Note

1

Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.18mg. (Requirement: ≤2mg per powder-free glove)

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

Sample Photo:



SGS authenticate the photo on original report only



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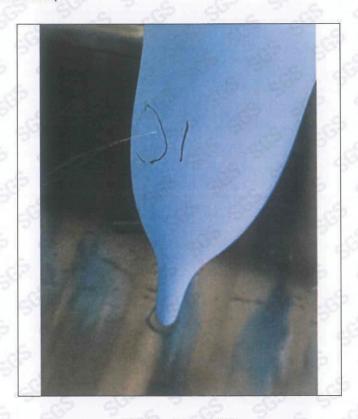


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Refer Photo (Watertightness test):



End of Report



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Prävention-mit-Kopf GmbH

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