
医用丁腈检查手套
MEDICAL NITRILE EXAMINATION GLOVES
INMBN-350
左右手通用
无粉
指檐
蓝色
包装：100支/盒 10盒/箱
净重：3.5 KG
毛重：4.5 KG
型号：中号
批号：20181102
生产日期：201811
有效期：五年
INTCO
英科医疗
股票代码 300677
医用丁腈检查手套
MEDICAL NITRILE EXAMINATION GLOVES
INMBN-350
左右手通用
无粉
指檐
蓝色
M
SIZE
中号
生产商：

英科丁腈手套材料清单

- 1. 厂家简介和产品图示
- 2. 营业执照及医疗器械备案证
- 3. 产品使用说明
- 4. 产品检测报告（多项）
- 5. ISO 13485认证
- 6. CE 认证
- 7. FDA认证
- 8. 欧么委员会符合性声明书

英科丁腈手套

英科医疗于2009年在山东省成立，是一家致力于医疗器械耗材研发、生产、营销的企业， 2017年7月深圳证券交易所上市。业务涵盖医疗防护、康复器械、检查耗材等，目前在全球拥有12家子公司，产品已经远销美洲、欧洲、亚洲、非洲、大洋洲的100+个国家和地区。

品牌： 英科医疗	品名： 一次性丁腈手套
材质： 丁腈化合物	尺码： XS S M L XL
类型： 无粉	长度： 9 寸
颜色： 白色、蓝色、粉色、紫色、黑色	

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

第一类医疗器械备案凭证

山东英科医疗制品有限公司：

根据相关法规要求，对你单位第一类医疗器械：医用 PVC 检查手套予以备案，备案号：鲁潍械备 20180031 号。

潍坊市食品药品监督管理局

（盖章）

日期：2018 年 10 月 30 日

第一类医疗器械备案凭证

山东英科医疗制品有限公司：

根据相关法规要求，对你单位第一类医疗器械：医用丁腈检查手套予以备案，备案号：鲁潍械备20180030号。

潍坊市食品药品监督管理局

（盖章）

日期：2018年10月30日

第一类医疗器械备案凭证

山东英科医疗制品有限公司：

根据相关法规要求，对你单位第一类医疗器械：医用乳胶检查手套予以备案，备案号：鲁潍械备20180029号。

潍坊市食品药品监督管理局

（盖章）

日期：2018年10月30日

第一类医疗器械备案信息表

备案号：鲁潍械备 20180031 号

备案人名称	山东英科医疗制品有限公司
备案人组织机构代码	91370781561439654L
备案人注册地址	青州市猛山工业园齐王路
生产地址	青州市猛山工业园齐王路
代理人	/
代理人注册地址	/
产品名称	医用 PVC 检查手套
型号/规格	型号：XS/S/M/L/XL。规格：10 支/盒、12 支/盒、20 支/盒、50 支/盒、60 支/盒、80 支/盒、100 支/盒等（可根据客户需求定制相应规格）。
产品描述	采用聚氯乙烯制造。有足够的强度和阻隔性能。非无菌提供，一次性使用。
预期用途	用于戴在医生手上对患者病情进行检查或触检。
备注	/
备案单位和日期	潍坊市食品药品监督管理局 备案日期：2018 年 10 月 30 日
变更情况	/

第一类医疗器械备案信息表

备案号：鲁潍械备 20180030 号

备案人名称	山东英科医疗制品有限公司
备案人组织机构代码	91370781561439654L
备案人注册地址	青州市猜山工业园齐王路
生产地址	青州市猜山工业园齐王路
代理人	/
代理人注册地址	/
产品名称	医用丁腈检查手套
型号/规格	型号：XS/S/M/L/XL。规格：10 支/盒、12 支/盒、20 支/盒、50 支/盒、60 支/盒、80 支/盒、100 支/盒等（可根据客户需求定制相应规格）。
产品描述	采用丁腈胶乳制造。有足够的强度和阻隔性能。非无菌提供，一次性使用。
预期用途	用于戴在医生手上对患者病情进行检查或触检。
备注	/
备案单位和日期	潍坊市食品药品监督管理局 备案日期：2018 年 10 月 30 日
变更情况	/

第一类医疗器械备案信息表

备案号：鲁潍械备 20180029 号

备案人名称	山东英科医疗制品有限公司
备案人组织机构代码	91370781561439654L
备案人注册地址	青州市猛山工业园齐王路
生产地址	青州市猛山工业园齐王路
代理人	/
代理人注册地址	/
产品名称	医用乳胶检查手套
型号/规格	型号：XS/S/M/L/XL。规格：10 支/盒、12 支/盒、20 支/盒、50 支/盒、60 支/盒、80 支/盒、100 支/盒等（可根据客户需求定制相应规格）。
产品描述	采用胶乳制造。有足够的强度和阻隔性能。非无菌提供，一次性使用。
预期用途	用于戴在医生手上对患者病情进行检查或触检。
备注	/
备案单位和日期	潍坊市食品药品监督管理局 备案日期：2018 年 10 月 30 日
变更情况	/

产品使用说明书

【产品名称】医用丁腈检查手套

【型号规格】型号：XS、S、M、L、XL。规格：10 支/盒、12 支/盒、20 支/盒、50 支/盒、60 支/盒、80 支/盒、100 支/盒等（可根据客户需求定制相应规格）

【备案人/生产企业/售后服务单位名称】山东英科医疗制品有限公司

【备案人/生产企业住所】山东省青州市猛山工业园齐王路

【生产地址】山东省青州市猛山工业园齐王路

【备案人/生产企业/售后服务单位联系方式】山东省青州市猛山工业园齐王路

电　话：0536 - 6136888　　邮编：262500

【医疗器械备案凭证编号】

【医疗器械生产备案凭证编号】

【医疗器械技术要求编号】

【产品性能、主要成分】用于戴在医生手上对患者病情进行检查或触检的用品。该产品采用丁腈胶乳制造。有足够的强度和阻隔性能。非无菌提供，一次性使用

【适用范围】用于防止医生与患者之间的交叉感染，适用于医用工作者、家庭清洁、护理人员

【注意事项】

- 产品使用对象为成人
- 请在10° C—30° C的环境下使用
- 穿戴前请修剪指甲，指甲太长或太尖容易导致手套破损
- 穿戴手套时，请勿戴戒指或其他饰品
- 本品为一次性用品，请勿反复使用

- 若包装破损，请勿使用
- 使用后的检查手套，请勿随意丢弃，以免污染环境

【禁忌症】

- 如有过敏现象，请立即停止使用
- 避免接触强化学物如酸、碱、有机溶剂等，可能会导致手套的性能衰退或损坏

【特别提示】

- 请将本品置于婴幼儿无法触及的地方，以免发生意外

【使用说明】启开包装盒封口，将手套从盒内取出戴好

【储存、运输条件、方法】 存放在相对湿度≤80%、无阳光直射、无腐蚀性气体和通风良好的室内

【生产日期】见标签

【有效期限】五年

【医疗器械标签所用的图形、符号、缩写等内容的解释】


10° C—30° C使用


遮光保存


避免雨淋


一次性使用


可回收


倒入垃圾桶

产品已通过CE认证

企业通过SGSISO13485：2003体系认证

企业通过SGS ISO 9001体系认证

企业通过FDA体系认证

企业通过美国测试标准

【其他应当标注的内容】无

【使用说明书编制日期】2018 年 10 月 18 日

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

PSB Singapore

Add value.
Inspire trust.

SUBJECT:

Testing of Disposable Nitrile Glove submitted by
Shandong Intco Medical Products Co., Ltd. on 18 Feb 2019.

TESTED FOR:

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

TEST DATE:

25 Feb 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Glove	Blue	/	M	217	Shandong Intco Medical Products Co., Ltd

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

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

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

Phone : +65-6885 1333
Fax : +65-6776 8670
E-mail: enquiries@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221

PSB Singapore

RESULTS:

Sample: Disposable Nitrile Glove, Size M

Table: Results for EN 455-1:2000

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	7	200	0	Passed

REMARKS:

1. The manufacturing lot no. was not provided by the client.

Yeo Poh Kwang
Higher Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo : Disposable Nitrile Glove, Size M

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

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

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

Sample Description	: METRO/MAKRO PROFESSIONAL NITRILE GLOVES, NON-POWDERED, BLUE
Sample Receiving Date	: SEP.12,2019
Testing Period	: SEP.12,2019 TO SEP.25,2019
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: EN 455-2-2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES
Test Result(s)	: PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	: THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

Remark: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

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

QDHL1909015461OT

Zhou Xinkuan, SK
Lab Manager

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

Test Conducted:

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

Number of test sample	:	26 Pieces
The type of gloves	:	examination/procedure gloves c)
Manufacturing batch code	:	/
Size	:	Examination/procedure gloves: M
Defects observed before testing	:	No defects

Clause	Test Items	Result	Note
5	Strength	---	---
5.2	Force at break	Pass	# 1
5.3	Force at break after challenge testing	Pass	# 1

Notes : #1 See result 1

Test Result:

1. Strength

Sample Quantity: 13pcs

Size	M												
Force at break(N)	7.8	8.5	8.0	9.0	9.4	8.9	6.8	7.1	8.2	8.9	8.3	8.6	8.4
Force at break after challenge testing(N)	7.8	7.6	8.3	7.6	6.5	6.1	8.4	7.4	6.8	6.8	8.5	7.2	6.0

Median value:

Force at break during shelf life (N): 8.4

Force at break after challenge testing (N): 7.4

Requirements: see table 3

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b)	c)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 6,0	≥ 3,6

a) Requirements for all surgical gloves.
b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene)..
c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).

Sample Photo:

Received sample

SGS authenticate the photo on original report only

End of Report

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Test Report

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

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

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

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

****

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

Vincent Feng
Technical Manager

3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666*2013 f (86-21) 54500353 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666*2013 f (86-21) 54500353 e sgs.china@sgs.com

Test Conducted:

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

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

Clause	Test Items	Result	Note
4.4	Powder	Pass	#1

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

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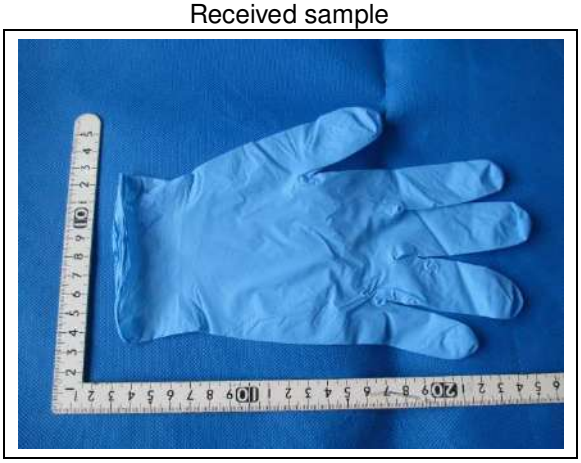
Sample Photo:

Received sample



SGS authenticate the photo on original report only

End of Report

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中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666*2013 f (86-21) 54500353 e sgs.china@sgs.com

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

NO. 9888, QIWANG ROAD, NAOSHAN INDUSTRY PARK, QINGZHOU, SHANDONG, CHINA

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1703010315MD DATE: MAR. 22, 2017

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

Sample Description	: CLEAR VINYL EXAMINATION GLOVES
SGS Ref. No.	: QDHL1703004208OT
LOT No.	: 5516-20170101
Sample Receiving Date	: MAR. 10, 2017
Testing Period	: MAR. 10, 2017 TO MAR. 22, 2017
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: 1. FREEDOM FROM HOLES (ASTM D5250-06 (REAPPROVE 2015) CLAUSE 6.1.2) 2. PHYSICAL DIMENSIONS (ASTM D5250-06 (REAPPROVE 2015) CLAUSE 6.1.3) 3. PHYSICAL PROPERTY CHARACTERISTICS (ASTM D5250-06 (REAPPROVE 2015) CLAUSE 6.1.4) 4. POWDER RESIDUE FOR POWDER FREE GLOVES (ASTM D5250-06 (REAPPROVE 2015) 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

Melody Zhang
Authorized Signatory

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Test Conducted:

ASTM D 5250-06 (Reapprove 2011) Standard Specification for Poly (vinyl chloride) Gloves for Medical Application

Number of test sample	:	244 pcs
Accelerated aging condition	:	70 ℃, 72 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 materials is < 35 IRHD as per client's claim.

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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	250	96	0.057	0.119
	2	252	98	0.055	0.126
	3	250	95	0.060	0.120
	4	240	95	0.056	0.168
	5	245	95	0.058	0.094
	6	250	95	0.056	0.099
	7	246	97	0.056	0.142
	8	250	96	0.056	0.083
	9	250	96	0.051	0.106
	10	247	96	0.056	0.104
	11	246	95	0.057	0.154
	12	247	96	0.051	0.105
	13	250	96	0.058	0.107
	Found	0	0	0	0

Requirements: see table 1

Table 1 Dimensions and tolerances

Designation	Size							Tolerance, mm
	6	6.5	7	7.5	8	8.5	9	
Width by size, mm	76	83	89	95	102	108	114	6
Width by small, medium, large, and extra large, mm	small		medium		large		x-large	
Large, mm	85		95		105		115	5
Length, mm	230 for all sizes							Min.
Thickness, mm								
Finger	0.05							Min.
Palm	0.08							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	16.2	500.0	16.5	516.7
2	20.0	670.0	17.8	600.0
3	18.1	526.7	18.5	536.6
4	14.8	446.7	14.3	413.3
5	19.1	503.3	14.6	470.0
6	18.0	533.3	13.5	336.7
7	15.1	479.9	18.9	603.3
8	14.8	430.0	16.8	516.7
9	15.4	523.3	16.1	460.0
10	16.9	513.3	17.1	540.0
11	15.9	523.3	17.8	493.3
12	18.1	532.0	15.4	500.0
13	18.3	603.3	17.4	536.6
Found	0	0	0	0

Requirements: see table 2

Table 2- Physical requirements

Tensile strength, MPa, Min.	Ultimate Elongation,% Min.
11	300

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	0.60	Pass

Sample Photo:

Sample as received (Size M)

SGS authenticate the photo on original report only

End of Report

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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.	: QDHL1703004209OT
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

Melody Zhang
Authorized Signatory

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Test Conducted:

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

Number of test sample	:	244 pcs
Accelerated aging condition	:	70 ℃, 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.

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	unisize	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

Sample Photo:

Sample as received (Size M)

SGS authenticate the photo on original report only

End of Report

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TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Intco Industries Co., Ltd.
3F., Building 9, Block F,
No.188 Xinjun Ring Rd., Minhang
201114 Shanghai
China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products and additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60079436 0001

An audit was performed. Report No.: 15044656 002

This Certificate is valid until: 21.08.2016

Certification Body

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 13.11.2012

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60079436 0001
Report No.: 15044656 002

Organization:
Intco Industries Co., Ltd.
3F., Building 9, Block F,
No.188 Xinjun Ring Rd., Minhang
201114 Shanghai
China

Scope:

Products:

- Disposable Electrosurgical Active Electrodes (Electrosurgical Pencils)
- Disposable Patient Plate (Grounding Pads)
- Disposable ECG Electrodes
- Wheelchairs
- Cold Packs
- Hot Packs
- Hot/Cold Packs
- Warmers
- Examination Gloves
- Disposable Non-woven Products
- Cool Gel Mats
- Hot/cold Pads
- Cooling Patch

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

X. Ren

Date: 2012-11-13

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60079436 0001
Report No.: 15044656 002

Organization:
Intco Industries Co., Ltd.
3F., Building 9, Block F,
No.188 Xinjun Ring Rd., Minhang
201114 Shanghai
China

Scope:

Sites included:
Shanghai Intco Electrode Manufacturing Co., Ltd.
No. 1358, Hubin Road, Fengxian District
Shanghai 201417, P. R. China

Manufacture of Disposable ECG Electrodes, Disposable Electrosurgical Active Electrodes (Disposable Electrosurgical Pencils), Disposable Patient Plate (Grounding Pads)

Shanghai Intco Medical Supply Co., Ltd.
No. 1358, Hubin Road, Fengxian District
Shanghai 201417, P. R. China

Manufacture of Cold Packs and Hot Packs, Hot/Cold Packs, Warmers, Hot/Cold Pads

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-995.00.01-46

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

X. Ren

Date: 2012-11-13

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Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60079436 0001
Report No.: 15044656 002

Organization:
Intco Industries Co., Ltd.
3F., Building 9, Block F,
No.188 Xinjun Ring Rd., Minhang
201114 Shanghai
China

Scope:

Sites included:

INTCO (Zhenjiang) Machinery Co., Ltd.
No. 77 Yandunshan Road, Dagang Zhenjiang,
Jiangsu Province 212132, China

Manufacture of Wheelchairs, Cold Packs, Hot Packs, Hot/Cold Packs, Cool Gel Mats, Warmers

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Date: 2012-11-13

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

X. Ren

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.

PPE REGULATION (EU) 2016/425
MODULE C2 CERTIFICATE

Issued to:

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

This is to certify that the following products tested under SATRA reports referenced: STE0293607 & CHM0295494/2009/JH have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
	697024575		
2777/11804-01/E00-00	Blue 697024575 601-605 Violet 69724575 631-635 White 69724575 641-645 Black 69724575 651-655	Disposable nitrile Non-sterile glove	EN ISO 374-1:2016+A1:2018 Type B

Dated: 5th March 2020

This certificate is valid until: *March 2021*

Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited

CE

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.

SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P. Republic of Ireland.
(Notified Body number 2777)
Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

Shandong Yinghong Medical Products Co., Ltd.
No. 15 East Road, Hongrun Industry Park, Qingzhou, Shandong, China
Tel: 0086-536-5768606

INDICATIONS FOR USE

Applicant: Shandong Yinghong Medical Products Co., Ltd.

510(k) Number: K110981

Device Name: Patient Nitrile Examination Gloves, Powder free, Non-Sterile, Blue Color

Indications of Use:

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (21CFR 880.6250)

Prescription Use _____ Over the Counter Use ___X___

Factory Initials _____

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110981

证书编号：2010100305S

TESTING
CNAS L2954

Sanitation & Environment technology Institute, Soochow University, Final Report

Report Number: SDWH-2012-22232

Endotoxin Test (TAL) of disposable nitrile gloves using EN 455-3:2006(5) Medical gloves for single use - Part 3: Requirements and testing for biological evaluation

Gel-Clot Limit Test

Sponsor

Shandong Intco Medical Products Co., Ltd

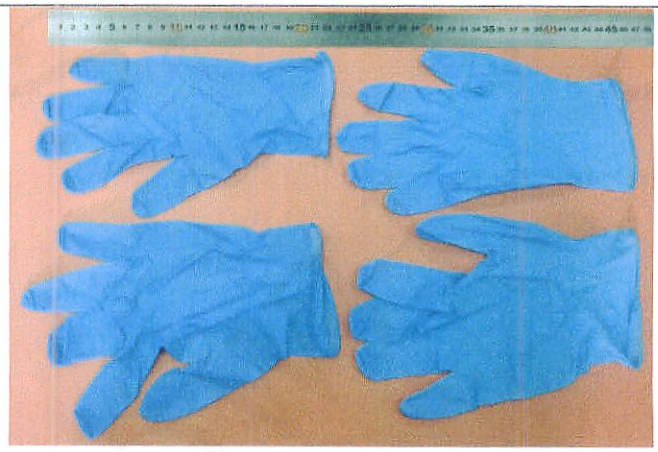
Sanitation & Environment Technology Institute, Soochow University
Tel: 0512-65880038 Fax: 0512-65880058 Email:sudaweihuan@163.com PC: 215123
Add: No.199 Ren'ai Road, Suzhou Industrial Park, China http://yxbfzb.suda.edu.cn

CONTENTS

SUPPLEMENTARY EXPLANATION

1. If the analysis report requires modification please raise the matter within 15 days of receiving the report, otherwise the request for modification will not be accepted.
2. The test report is void without test institute's seal.
3. The test report is only valid when signed by the persons who edited, checked and approved it.
4. Any erasure renders the report null and void.
5. The test result is only valid for the sample provided.
6. The copyright of analysis report is reserved by the analysis institute. If a copy is required, please get permission from the institute first. Only complete copies of the test report may be made.

STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2012-08-06
Protocol No:	SDWH-PROTOCOL-2012-22232
Protocol Effective Date:	2012-08-06
Technical Initiation Date:	2012-08-28
Technical Completion Date:	2012-08-28
Final Report Completion Date:	2012-08-29

Edited by : Xu lin 2012-08-30
Date

Checked by : Lixyin 2012-08-30
LI Xinyin/Study Director Date

Fangjy 2012-08-30
FANG Jing-yi / Medical Device Lab Director Date

Approved by : Zhang Tongcheg 2012-08-30
ZHANG Tong-cheng / Vice Director Date

苏州大学卫生与环境技术研究所 检测专用章

Sanitation & Environment Technology Institute, Soochow University

1.0 Study Summary

The Endotoxin Test (TAL) of disposable nitrile gloves using Gel-Clot Limit Test. All the sample solution were negative. Conclusion: Endotoxin concentration of sample solution was less than 0.5 EU/ml, and each pair of gloves was less than 20 EU under this test system.

2.0 Purpose

To detect the bacterial endotoxin on the test article.

3.0 Reference

EN 455-3：2006(5) Medical gloves for single use - Part 3:Requirements and testing for biological evaluation

4.0 Compliance

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS-CL01 Accreditation Criteria for the competence of testing and calibration laboratories)China National Accreditation Service for Conformity Assessment. Laboratory Accreditation Certificate No.CNAS L2954
Accreditation Criteria for the competence of the laboratories (Quality and Technical Bureau of Jiangsu Province Metrology Accreditation Certificate CMA 2010100305S)

5.0 Identification of test article

Test article name: disposable nitrile gloves
Sterilization Method: Not Supplied by Sponsor(N/S)
CAS/Code# : N/S
Size: 4S、M、L、XL
Lot/ Batch#: N/S
Physical State: Solid
Color: See Article Image
Density: N/S
Stability: N/S
Solubility: N/S
Storage Condition: Room Temperature
The information about the test article was supplied by the sponsor wherever applicable;

6.0 Definition

λ： Labeled Lysate Sensitivity
λc: Confirmation Lysate Sensitivity
L: The endotoxin limit of the sample

7.0 Equipments

Drying cabinet (SDWH-311)
Incubator (SDWH-313)
Vortex mixer（SDWH-093）

8.0 Regents

Tachpleus Amebocyte Lysate (TAL)

Manufacturer: Chinese Horseshoe Crab Reagent Manufactory CO., Ltd.
Contents: 0.2ml
Lot No.: 110604
Sensitivity: 0.5EU/ml

TAL Reagent Water (LRW)
Manufacturer: Chinese Horseshoe Crab Reagent Manufactory CO., Ltd.
Volume: 50ml
Lot No.: 100305

Reference Standard Endotoxin (RES)
Manufacturer: Chinese Horseshoe Crab Reagent Manufactory CO., Ltd.
Contents: 8EU
Lot No.: 101204

9.0 Materials

Depyrogenate all glassware and other heat-stable materials in temperature 250℃ at least 30minutes. The plastic apparatus should be free of detectable endotoxin and not to interfere with the test.

10.0 Method

10.1 Test for Confirmation of Labeled TAL Reagent Sensitivity

10.1.1 Prepare solutions test group and negative control as shown in the table

	Endotoxin Concentration/Solution to which Endotoxin is Added	Dilution Factor	Endotoxin Concentration	Number of Replicates
Test group	2λ/LRW	1	2λ	4
		2	1λ	4
		4	0.5λ	4
		8	0.25λ	4
Negative control	No//LRW	-	-	4

10.1.2 Mix a volume of the TAL Reagent (0.1ml/tube) with a equal volume of above solution respectively, sealed the tube and incubated at 37±1℃ for 60±2 min.

10.1.3 Criteria: To test the integrity of the gel, take each tube in turn directly form the incubator and invert it through about 180° in one smooth motion. If a firm gel has formed that remains in place upon inversion, record the results as positive. A result is negative if an intact gel in not formed.

The test is not valid unless the lowest concentration of the standard solutions shows a negative result in all replicate tests.

If this is not less than 0.5 λ and not more than 2 λ , the labeled sensitivity is confirmed and is used in tests performed with this lysate.

10.1.4 Calculate the confirmation TAL reagent sensitivity using the following equations:

$\lambda c = lg\text{-}1 (\sum X/4)$

where $\sum X$ is the sum of the log endpoint concentrations of the dilution series used.

10.1.5 Results: λ c =0.4204

Concentration	2.0 λ	1.0 λ	0.5 λ	0.25 λ	negative control
Replicate 1	+	+	+	-	-
Replicate 2	+	+	-	-	-
Replicate 3	+	-	+	-	-
Replicate 4	+	+	-	-	-

+: positive; -: negative

10.1.6 Conclusion:: The batch TAL test sensitivity meets the requirement。

10.2 Interfering Factors Test

10.2.1 λ =0.5 EU/ml; L=20 EU

10.2.2 Preparation of sample solution

Aseptic extracting the test article (test article to volume of vehicle) by TAL Reagent Water according to the table below:

Extraction ratio	Actual sampling	Extraction conditions	The pH value of the final extract	Whether the extract is clear or not
Each pair of gloves :40ml	Each one of the 4S、M、L XL:80ml	37 ℃,60min	7.0	Clear

The sample solution: 100% extraction solution.

10.2.3 Prepare solutions A, B, C and D as shown in the table

	Endotoxin Concentration/Solution to which Endotoxin is Added	Diluent	Dilution Factor	Endotoxin Concentration	Number of Replicates
A	none/sample solution	-	-	-	4
B	2λ/ sample solution	sample solution	1	2λ	4
			2	1λ	4
			4	0.5λ	4
			8	0.25λ	4
C	2λ/LRW	LRW	1	2λ	2
			2	1λ	2
			4	0.5λ	2
			8	0.25λ	2
D	none/LRW	-	-	-	2

10.2.4 Mix a volume of the LAL Reagent (0.1ml/tube) with a equal volume of above solution respectively, sealed the tube and incubated at 37±1℃ for 60±2 min.

10.2.5 Criteria: To test the integrity of the gel, take each tube in turn directly form the incubator and invert it through about 180° in one smooth motion. If a firm gel has formed that remains in place upon inversion, record the results as positive. A result is negative if an intact gel in not formed.

The test is not valid unless Solution A and D show no reaction and the results of Solution C confirms the labeled sensitivity.

If the sensitivity of the lysate determined in the presence of the sample solution under test of Solution B is not less than 0.5 and not greater than 2 , the sample solution does not contain factors which interfere under the experimental conditions used

10.2.6 Calculate the geometric mean endpoint concentration of solutions C and B using the following equations: Es=lg-1（ΣXs/2）; Et=lg-1（ΣXt/4）. Where Xs and Xt are logarithms of endpoint concentrations of solutions C and B, respectively.

10.2.7 Result

	A	B				C				D
Endotoxin Concentration	-	2λ	1λ	0.5λ	0.25λ	2λ	1λ	0.5λ	0.25λ	-
Number of positive tubes	0	4	3	1	0	2	1	1	0	0

Es=lg-1（ΣXs/2）=0.354

Et=lg-1（ΣXt/4）=0.420

10.2.8 Conclusion

The sample solution did not contain factors which interfere under the experimental conditions used.

10.3 Gel-Clot Limit Test

10.3.1 Prepare solutions A, B, C and D as shown in the table

	Endotoxin Concentration/Solution to which Endotoxin is Added	Number of Replicates
A	none/sample solution	2
B	2λ/ sample solution	2
C	2λ/LRW	2
D	none/LRW	2

10.3.2 Mix a volume of the TAL Reagent (0.1ml/tube) with a equal volume of above solution respectively, sealed the tube and incubated at 37±1℃ for 60±2 min.

10.3.3 Criteria: To test the integrity of the gel, take each tube in turn directly form the incubator and invert it through about 180° in one smooth motion. If a firm gel has formed that remains in place upon inversion, record the results as positive. A result is negative if an intact gel in not formed.

The test is not valid unless both replicates of Solution B and C are positive and those of Solution D are negative.

10.3.4 Criteria Results of Gel-Clot Limit Test

A		B		C		D	
-	-	+	+	+	+	-	-

+: Positive; -: Negative

10.3.5 Conclusion

Endotoxin concentration of sample solution was less than 0.5 EU/ml, and each pair of gloves was less than 20 EU under the experimental conditions used.

11.0 Record Storage

All raw data pertaining to this study and a copy of the final report are retained in designated SDWH archive.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH-2012-22233

Residual Powder test of disposable nitrile gloves for EN 455-3 （2006） Method

Sponsor

Shandong Intco Medical Products Co.，Ltd.

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CONTENTS

SUPPLEMENTARY EXPLANATION

1. If the analysis report requires modification please raise the matter within 15 days of receiving the report, otherwise the request will not be accepted.
2. The test report is void without test institute's seal.
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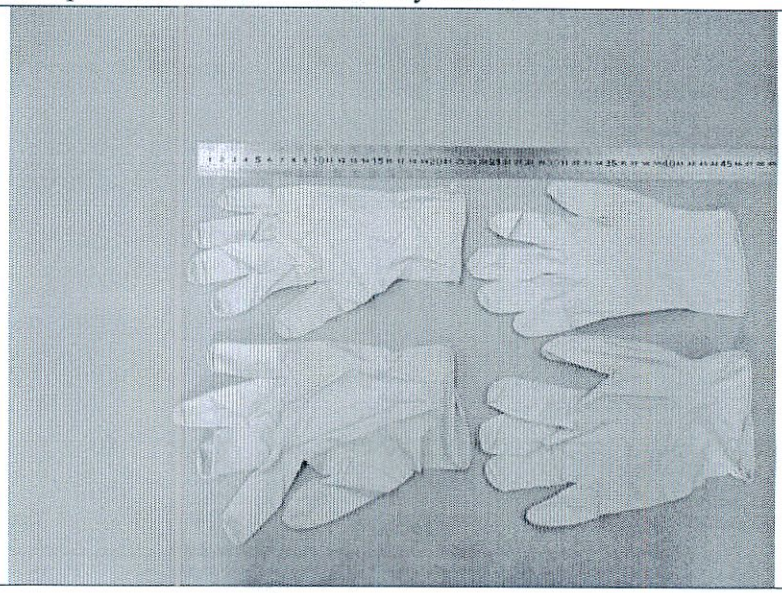
7. *Detection of the project 's application to join the CNAS recognition ability.

Sanitation & Environment Technology Institute, Soochow University, Test Report

Test Article	disposable nitrile gloves
Sample Supplier	Shandong Intco Medical Products Co.，Ltd.
Size	4S、M、L、XL
Lot/ Batch	N/S
The information about the test article was supplied by the sponsor wherever applicable	
Testing Performed	Residual Powder test
Receiving Date	2012-08-06
Technical Initiation Date	2012-08-22
Test Completion Date	2012-08-22
Test Condition	Temperature 20.0℃ humidity 62.0%
Sample Image	

Edited by: shen ming

Checked by: Li Haiying

Approved by: Zhang Yongjun

Sanitation & Environment Technology Institute, Soochow University

Date: 2012-8-30

1.0 Study Summary

This test using EN 455-3 (2006) Medical gloves for single use Part 3: Requirements and testing for biological evaluation. Four sizes samples each of five gloves, a total of 20 gloves. The surfaces of a glove are washed with water to remove the water-insoluble powder which is then determined by filtration followed by weighing.

2.0Purpose

This test using EN 455-3 (2006) Medical gloves for single use Part 3: Requirements and testing for biological evaluation. Under the experimental conditions of sample measured residual dust to make medical evaluation.

3.0Reference

Medical gloves for single use Part 3: Requirements and testing for biological evaluation (EN455-3:2006)

Medical gloves — Determination of removable surface powder (EN ISO 21171:2006)

4.0 Experiment design

4.1 Reagents

Wherever water is called for, distilled or deionized water shall be used.

4.2 Equipment

4.2.1 Electronic balance（SDWH404）

4.2.2 Drying oven（SDWH400）

4.2.3 Electric suction device（SDWH430）

4.2.4 Adjustable multi-purpose oscillator（SDWH023)

4.3 Experimental Procedure

4.3.1 Prior to use, all glassware and tweezers shall be rinsed with deionized or distilled water.

4.3.2 Use a 47 mm, 2.7 μm pore size glass microfiber filter and Electric suction device（SDWH430）. Use of a TFE-fluorocarbon or equivalent-rimmed housing base is recommended if filters adhere or tear upon removal from glass-rimmed surface.

4.3.3 Remove the filter from the filtration apparatus and transfer it to a rinsed and dried glass petri dish or equivalent. Dry in Drying oven（SDWH400）at 100±5°C for 1 h. Store the dried filter in a desiccator prior to use. Before use, pre-weigh the dried filter, weighing immediately by Electronic balance（SDWH404）after removal from the desiccator.Record the weigh as USE_b

4.3.4 Randomly select five gloves from each lot to be evaluated. Gently remove glove from original container.

4.3.5 Place 500 mL of deionized or distilled water into a 1000 mL flask. Water used in this procedure should be at 20 to 25°C, Place a glove into the beaker/flask with 1 to 3 cm of the cuff area stretched over the lip, Hold a portion of the cuffaway from the lip to vent air from the beaker/flask

and add 250 mL of deionized or distilled water to the inside of the glove, making certain the upper cuff is rinsed as the water is poured.

4.3.6 Cap the flask with a rubber stopper or other secure cover and agitate for 30 s on Adjustable multi-purpose oscillator（SDWH023) with a minimum side-to-side or rotational speed of 1.7 Hz (100 cycles/min)

4.3.7 Remove the cap and pour the water from the inside of the glove into a 600 mL glass beaker. Repeat 4.3.5～4.3.7 with the remaining four samples using the same 250 mL of water contained in the 600 mL glass beaker and the same 500 mL of original water

4.3.8 Pour the water from the 600 mL glass beaker and the beaker/flask through the Electric suction device（SDWH430）unit containing the weighed filter. Rinse the beaker/flask, cap, filter housing and any other portions of the test apparatus that may contain residual powder to ensure all powder extract is filtered.

4.3.9 Remove the filter and dried glass petri dish or equivalent. Dry in Drying oven（SDWH400） at 100±5°C for 1 h. Cool in a desiccator for 30 min prior to weighing on Electronic balance （SDWH404）. Record the weigh as USE_a

4.3.10 *Blank Control*—Using a beaker/flask and water identical.

4.3.11 filter identical to that described in4.3 2, filter 1000 mL of the water. Dry, desiccate, and weigh the filter by Electronic balance（SDWH404）. Record the weigh as B_b

4.3.12 Put the glass microfiber filter Establish a Blank Control for each of lot.Filter 1000 mL of the water in the Electric suction device（SDWH430）.

4.3.13 Dry, desiccate, and weigh the filter as the procedure 3. Record the weigh as B_a

4.4 Calculation

Caculate the result as ： $\frac{USE_a—USE_b—（B_a--B_b）}{20}$

The result is the powder mass per glove in milligrams.
containing 2 mg or less powder is a powder-free glove and more than 2 mg is a powdered glove

5.0 Results

Testing Performed	Results
* Residual Powder test （the powder mass per glove in milligrams）	0.55

6.0 Conclusion

The testing results showed that the batch of disposable nitrile gloves are powder-free gloves for qualified products

7.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

8.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH-2012-22234

Protein Test of disposable nitrile gloves for EN 455-3（2006）Method

Sponsor

Shandong Intco Medical Products Co., Ltd.

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CONTENTS

SUPPLEMENTARY EXPLANATION

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7. *Detection of the project 's application to join the CNAS recognition ability.

Sanitation & Environment Technology Institute, Soochow University, Test Report

Test Article	disposable nitrile gloves
Sample Supplier	Shandong Intco Medical Products Co.， Ltd.
Size	4S、M、L、XL
Lot/ Batch	N/S
The information about the test article was supplied by the sponsor wherever applicable	
Testing Performed	Protein Test
Receiving Date	2012-08-06
Technical Initiation Date	2012-08-21
Test Completion Date	2012-08-21
Test Condition	Temperature 22.0℃ humidity 63.5%
Sample Image	

Edited by: Shen Ming

Checked by: Li Haijing

Approved by: Zhang Jonjie

Sanitation & Environment Technology Institute, Soochow University

Date: 2012-8-22

1.0 Study Summary

This test using EN 455-3 (2006) Medical gloves for single use Part 3: Requirements and testing for biological evaluation. Four types of specifications samples each uniform sampling two identical gloves, divided into four pairs, for each pair of gloves, the second glove moderate stuffed previous glove, and then extracted, acid precipitation, re-dissolving step, by spectrophotometer , and the absorbance was measured at 750nm .

2.0Purpose

This test using EN 455-3 (2006) Medical gloves for single use Part 3: Requirements and testing for biological evaluation. Make a medical evaluation of the sample under the test conditions the protein content.

3.0Reference

Medical gloves for single use Part 3: Requirements and testing for biological evaluation
(EN455-3:2006)
ASTM D 5712:2010, Standard test method for analysis of protein in natural rubber and its products

4.0 Experiment design

4.1 Reagents

Whenever water is called for distilled or deionized water should be used. All other reagents should be of analytical quality.

4.1.1 N-tris-[Hydroxymethyl]-methyl-2-aminoethanesulfonic acid (TES), hemisodium salt.

4.1.2 Extraction buffer, 0,1 M, prepared by dissolving 24 g TES (A.3.2.1) in 1 Lwater. Any equivalent buffering system can be used provided the solution has sufficient buffering capacity to hold a pH of 7,4 $\pm$0,2 in the glove extracts.

4.1.3 Dye solution, Bromophenol blue, sodium salt solution, prepared by dissolving 100 mg bromophenol blue in 1 Lof water. Prepare a fresh solution every four weeks.

4.1.4 Reagent A, Copper reagent (alkaline copper tartrate or copper citrate solution).

4.1.5 Reagent B, Diluted Folin reagent.

4.1.6 Sodium hydroxide, 0,1M aqueous solution

4.1.7 Sodium deoxycholate (DOC),3,47mM,prepared by dissolving 0,15g sodium deoxycholate in water and diluting with water to 100 ml. Do not use this solution more than four weeks after it has been prepared.

4.1.8 Trichloroacetic acid (TCA), 4,4 mM in water, prepared by dissolving 72 g TCA in water and diluting with water to 100 ml.

4.1.9 Phosphotungstic acid (PTA), prepared by dissolving 72 g PTA in water and diluting with water to 100 ml. Do not use this solution more than four weeks after it has been prepared.

4.1.10 Ovalbumin, from chicken egg2) lyophilized, salt-free.

4.1.11 Protein standard solutions Prepare a solution of ovalbumin with a nominal concentration of 1 mg/ml by dissolving 25 mg ovalbumin in 25 ml extraction buffer Filter the solution through a 0,22 µm filter and determine the true concentration of ovalbumin by using an UV spectrophotometer to measure the absorbance at 280 nm using a quartz cuvette . If the absorbance is divided by 0,7153) it will give the exact concentration in mg/ml. The solution is stable for 2 days under refrigeration or for 2 months frozen at -18 °C. Thawing requires heating to 45 °C for 15 min.

Prepare serial dilutions of the protein stock solution using the extraction buffer , to make solutions with nominal concentrations of about 100 µg/ml, 60 µg/ml, 35 µg/ml, 10 µg/ml, 0 µg/ml. Use extraction buffer as a blank.

4.2 Equipment

4.2.1 Adjustable multi-purpose oscillator (SDWH023)

4.2.2 Electronic balance (SDWH404)

4.2.3 Centrifuge (SDWH117)

4.2.4 UV-visible spectrophotometer (SDWH391)

4.3 Experimental Procedure

4.3.1 Extraction

4.3.1.1 The four types of specifications of each uniform sample to sampling two identical gloves.

4.3.1.2 Mark the cuff of one glove of each pair at a point (200 ± 10) mm from the tip of the middle finger and weigh the glove (m_1) to the nearest 0,1 g. For each pair, insert the second glove inside the marked one so that they fit together.

4.3.1.3 Pour into the inner glove a sufficient quantity of dye solution to fill all five fingers.Introduce 25 ml extraction buffer (4.1.2)at 25 °C between inner and outer gloves. For larger gloves this volume may be increased to a maximum of 50 ml. Remove most air bubbles and seal the gloves with the clamp at the 20 cm mark so as to produce a watertight seal

4.3.1.4 Fix the gloves to the shaker and shake for 120 min at25 °C.

4.3.1.5 Remove the clamp and separate the gloves carefully. Take care not to contaminate the extract with the dye solution. If the extract is coloured blue, it shall be discarded and the extraction repeated with fresh gloves.

4.3.1.6 Carefully transfer the extract into a centrifuge tube and clarify the extract either by centrifugation at not less than 2000 g for 15 min or filtration through a single use filter unit or a combination of both as appropriate. Either store the resulting clear solution refrigerated at 2 °C to 8 °C and carry out the determination within 48 h or alternatively freeze aliquots of the solution at -18 °C or lower for a period not exceeding 2 months before analysis.

4.3.1.7 Cut the section of the cuff above the 20 cm mark from the extracted outer glove, wipe the liquid off the surface with tissue, allow to dry at room temperature and weigh it to the nearest 0,1 g (m_2). Calculate the mass (m) of the extracted part of the glove as follows:

$$m = m_1 - m_2$$

4.3.2 Precipitation

4.3.2.1 The four types of specifications sample extracts were uniformly mixed, Accurately transfer 1 ml each of the blank, protein standard solutions and the four glove extracts into micro tubes. Add 0,1 ml of DOC mix by vortexing and allow to stand for 10 min. Add 0,1 ml of TCA and 0,1 ml PTA mix by vortexing and allow to stand for a further 30 min.

4.3.2.2 Centrifuge at 6000 g for 15 min. Decant the supernatant liquid and drain for 5 min by inverting each centrifuge tube on an absorbent paper.

4.3.3Redissolution

Add 0,2 ml of 0,1 M sodium hydroxide solution to each tube including the blank. Mix on a vortex mixer to re-dissolve the precipitated proteins. Ensure that the proteins are completely re-dissolved to a clear solution. Depending on the glove this sometimes needs an overnight standing refrigerated at (5±3) °C. If any precipitate remains, add a further, measured quantity of the sodium hydroxide solution by 0,2 ml increments up to a total of 1 ml and use a 0,2 ml aliquot for subsequent steps. It can be useful to dilute the extract of such samples prior to precipitation

4.3.4 Colour development

Add 0,125 ml Reagent A into each micro tube containing the re-dissolved protein solutions including the blank. Mix well. Add 1 ml Reagent B, cap the tube, vortex and allow the colour to develop fully for 30 min. Should precipitation occur at this stage, centrifuge or filter to remove the precipitate before measuring the absorbance.

4.4 Calcultion

4.4.1 Transfer the solution to a cuvette and measure the absorbance against the blank at a specific wavelength in the range 600 nm to 760 nm.

4.4.2 Calibration Curve-The spectrophotometric absor-bance measurements of the redissolved standard protein solu-tions in the Lowry assay are plotted on the ordinate against their concentration in ug/mL on the abscissa. The calibration curve is curvilinear over the protein concentration range of 0 to 200 ug/mL of standard solutions. The calibration data should be curve-fit to a second degree polynomial function (quadratic) and forced through the origin of the calibration plot. The concentration (C) of the protein analyte in the test specimen extract is read from the calibration curve in ug/mL.

μ g/ml	0	10	35	60	100
A	0	0.041	0.125	0.19	0.284

$y = -0.0000101\ x^2 + 0.0038435\ x$ $R^2 = 0.9992487$

Determine the concentrations of the extracted samples (C) in Ug/mL extract by reading them directly from the calibration curve.

A nonlinear relationship between absorbance and con-centration exists when the dose-response profile of the absor-bance readings versus protein concentration ofthe Lowry assay is curvilinear. Since the Lowry calibration curve is typically curvilinear, the calibration data of protein standards should be fitted to a quadratic nonlinear equation that represents the shape of the data. Curve-fitting of data may be performed by the spectrophotometer or attached instrument with a pre-programmed microprocessor or independently through the use of an external computer. In the later case, the calibration data may be curve-fit using the following quadratic equation:

$$A_{std} = a_1 * c + a_2 * c^2$$

where:

Astd : absorbance readings of the standard protein solutions,

a1 : the slope coefficient at low standard protein concen-trations,

a2 :coeggicent that defines she cuevature of the standard curve,and

c: concentration of the standard protein solutions in ug/ml

4.4.3 The protein content of each sample is given by

$$P = \frac{V \cdot C \cdot F}{m}$$

where :

P is extractable protein in μg/g of glove;

V is the volume of extraction medium used in ml;

C is the protein concentration of the extract in μg/ml;

F is the dilution factor; F is the real volume of NaOH solution in ml used to re-dissolve the protein divided by 0,2.

5.0 Results

Testing Performed	limit	Results
*Protein Content, μ g/g	>10	74.4

6.0 Conclusion

Been tested under the environmental conditions of the experiment, the batch of disposable nitrile gloves detection value of the sample protein content to meet the standard requirements, are qualified products

7.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

8.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.