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。


医用丁腈检查手套
MEDICAL NITRILE EXAMINATION GLOVES
INMBN-350
左右手通用 非灭菌 无粉 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 非灭菌 无粉 蓝色
M
SIZE
中号
生产商:

品牌： 英科医疗	L-) 口口否. 一次性丁腈手套
材质： 丁腈化合物	尺码： XSSM LXL
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 9137078[redacted] 1-1

[redacted]司

其他有限责任公司

[redacted]路

法定代表人 刘方毅

肆亿零陆佰万元整

2010 年 08 月 23 日

2010 年 08 月 23 日至 2030 年 08 月 23 日

丁睛手套、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

月 °2 日

提示：1.每年 1 月 I 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 4 金翌不另行嘉 9 |

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:

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

[redacted]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 2[redacted]1 号。

[redacted]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

[redacted]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：医用丁睛检查手套予以备案，备案号：鲁潍械备[redacted]30号。

[redacted]

旧盖沮间

蠼理局食品药品监管

日期 k 骑 18 年 10 物 0 日

第一类医疗器械备案凭证

[redacted]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 [redacted]9 号。

第一类医疗器械备案信息表

备案号：鲁潍械备 [redacted]

备案人名称	[redacted]有限公司
备案人组织机构代码	91370781561439654L
备案人注册地址	[redacted]
生产地址	[redacted]
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	潍坊市件药營督管理局 ； [redacted]%營 018 年 10 月「30 0 1
变更情况	/

[redacted]

第一类医疗器械备案信息表

备案号：鲁潍械备 201[redacted]号

备案人名称	[redacted]
备案人组织机构代码	9137[redacted]
备案人注册地址	[redacted]
生产地址	[redacted]
代理人	/
代理人注册地址	/
产品名称	医用丁睛检查手套
型号/规格	型号：XS/S/M/L/XLo 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	采用丁睛胶乳制造。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	[redacted] 潍坊市件蕴臂”管理局 备案日^^18 年 10 甬顷 0
变更情况	/ 7W

第一类医疗器械备案信息表

备案号：鲁潍械备 201[redacted]

备案人名称	[redacted]
备案人组织机构代码	91370781561[redacted]
备案人注册地址	[redacted]
[redacted]	青州市猫山工业园齐王路
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/XLo 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	[redacted]^嚨草局 备案日^輪。18 年 10 饥 4） 0
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[redacted]

【备案人/生产企业住所[redacted]

【生产地址】[redacted]

【备案人/生产企业"竊月賤•单位联系方式】[redacted]

电 话：0536-[redacted]

【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 W80%、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

避免雨淋

一次性使用

倒入垃圾桶

CE 产品已通过 CE 认证

企业通过 SGSIS013485 2003 体系认证：

企业通过 SGS ISO 9001 体系认证

血每企业通过 FDA 体系认证

蝇

INTBiNATIONAL 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

TUV SUD PSB

Laboratory:
TUV SUD 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:
TUV SUD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01 re
118221

Singapo
W

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 TUV SUD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TUV SUD 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. TUV SUD 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 TUV SUD 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 TUV SUD PSB or to the report or results furnished by TUV SUD PSB in any advertisements or sales promotion.
5. Unless otherwise stated, the tests were carried out in TUV SUD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

SGS

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, NONPOWDERED, 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) Conclusion	: PLE ASE REFER TO THE FOLLOWING PAGE(S) :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.

Zhou Xinkuan, SK
Lab Manager

SGS Certet, No. 143,3udiou Road, Laostan Dlstrid, Qingdao. China 266101

www^gsgroup.co

Test Conducted:

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

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

Notes #1 See result 1

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

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

SGS Certw; No. 143,3udiou Road, Laostan EXstricI, Qingdao. China 266101
t (86-532)63996888 f (86-532)80891955
www^gagrou p.con.cn e

SGS

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

SGS Certet, No. 143,3udiou Road, Laostan Dlstrid, Qingdao. China 266101

om.cn
t (86-532)63999888 f (86-532)80891955 e sgs.ctiina@sgs.com

SG$

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

1*7 Buiing, No.889. Yishan Read Xuhii DistktShangte, *Dim* 200233 t
(86-21)61402666*2013 f (86-21)54500353 vww.sgsgroup.com.cn
中国•上海•袂汇也宜山路 889 号 3 号梭 邮编： 200233 1(86-21)61402666*2013 f (86-21)54500353 0 sgs.chhaj 她 am

Test Conducted:

Clause	Test Items	Result	Note
4.4	Powder	Pass	#1

EN 455-3-2006 Medical gloves for single use — Part 3:Requi「ements 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

Note:
1. Test according to EN ISO 21171-2006.
2. The quantity of powder was 0.2mgV2mg.

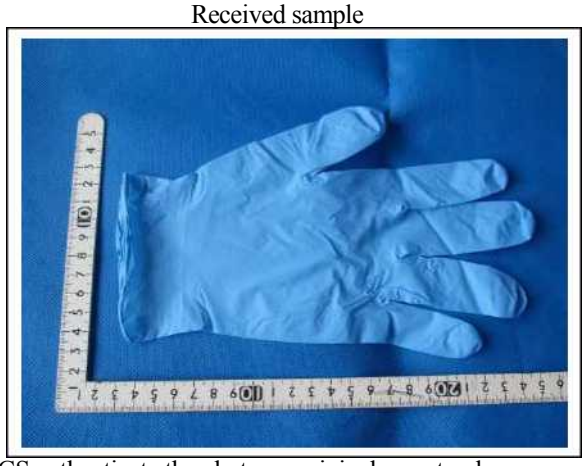
I7 Buiing, No.889. Yishan Read Xuhii DistktShangte, *Dim* 200233 t (86-21)61402666*2013

SG$

f (86-21)54500353
中国•上海•袂汇也宜山路 889 号 3 号梭 邮编： 200233
vww.sgsgroup.com.cn
1(86-21)61402666*2013 f (86-21)54500353 0 sgs.chhaj 她 am

Sample Photo:

Received sample



SGS authenticate the photo on original report only

End of Report

I7 Buiing, No.889. Yishan Read Xuhii DistktShangte, *Dim* 200233 t
(86-21)61402666*2013 f (86-21)54500353 vww.sgsgroup.com.cn
中国•上海•袂汇也宜山路 889 号 3 号梭 邮编： 200233 1(86-21)61402666*2013 f (86-21)54500353 0 sgs.chhaj 她 am

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 Zhang
Authorized Signatory

14« Boidng No389.倆 an Rood. Xuhu asm Shang China 200233
中国 上海徐汇区虹漕路88将4号楼 *邮* 200233
t (86) 400 960 9661 f (86-21) 6115 6899 t (86) 400 960 9661 f (86-21)61156899
www 釦 sgmup.8m.cn e sgs.chna^30sco m

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 °C, 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.

l4*Bjidn9 N0389 Y^ft^.XLiua$rclSrB^.Cr!ke 200233 t (86)4009609661 f (86-21)61156899 www.sgsgroup.com.cn
中 DO ·上海·徐汇区宜山路 88 捋 4 号楼 邮编 200233 1(86)4009609661 f (86-21)61156899 e sgs.chna©sgscom

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.

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

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

Table 2- Physical requirements

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

SG$

中 DO ·上海•徐汇区宜山路 88 捋 4 号楼 邮编 200233 1(86)4009609661 f (86-21)61156899 e sgs.chna©sgscom

SG$

Sample Photo:

Sample as received (Size M)

SGS authenticate the photo on original report only

中DO •上海•徐汇区宜山路 88 捋 4 号楼 鄭* 200233 t (86) 400 960 9661 f (86-21) 6115 6899 t (86) 400 960 9661 f www 鉬 sgmup.8m.cn e

End of Report

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

Melody

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

Melody Zhang
Authorized Signatory

Test Conducted:

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

Number of test sample	244 pcs
Accelerated aging condition Defects	70 °C, 166 h
observed before testing Test Result	No defect
	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	6^	7	7 贝	8	8^	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.

SG$

Test Repor[redacted] Page: 4 of 5

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 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

中 DO • 上海•徐汇区宜山路 88 捋 4 号楼 邮编 200233 1(86)4009609661 f (86-21)61156899 e
sgs.chna©sgscom

TUVRheinland

Certificate

The Certification Body of
TUV 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

:当芬
X *

Akkreditiert durch
Zentralstelle der Lfinder fur Gesundheitsschutz bei Arzneimilteln und Modizinprodukten
ZLG-ZQ-995.00.01-46

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle
X. Ren

Date 13.11.2012

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

TUVRheinland

TUV Rheinland
LGA Products GmbH
TillystraBe 2, 90431 Niirnberg

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

Akkreditiertdurch
Zentralstelle der Lander fOr Gesundheitsschutz bei Arzneimitleln und Medizinprodukten
ZLG-ZQ-995.00.01-46

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle
X. Ren

Date: 2012-11-13

-Cooling Patch

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

TUVRheinla^d

Doc. 2/3, Rev. 0

TUV Rheinland
LGA Products GmbH
TillystraBe *2,* 90431 Niirnberg

Scope:

Sites included:

Shanghai Intco Electrode Manufacturing Co.z Ltd. No.⊥358, 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 Packsz Warmers, Hot/Cold Pads

Akkreditiert durch
Zenlralstella der Lander fur Gesundheitsschutz bei Arzneimitteln
X **. *yf* und Medizinprodukten**
ZLG-ZQ-995.00.01-46

Certification Body

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

Date: 2012-11-13

TUV Rheinland
LGA Products GmbH
TillystraBe *2,* 90431 Nurnberg

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
Zentralslelle der Lender fUr Gesundheitsschutz bei Arzneimitleln und Medizinprodukten
甘义*k ZLG-ZQ-995.00.01-46

Date: 2012-11-13

Certification Body
X. Ren

Compliance Report

Applicant: [redacted]
Address: [redacted]

Product: Vinyl Examination Gloves
Type: XS, S, M, L,XL

Product Classiilcation: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and (csl report support the self declaration ibr the devices listed above. The test report and the technical Illes are the annex of this report and should be used together.

Where the manulacturer affix*s the CE marking to the product listed they must ensure that all the requirenients of the appropriate EU directivc(s) have and continue to be met.

This report is not a certificate of conform ity.

No. 01919
Initial Issue Date: 20 Apr 2012
Reissue Dale:28 Dec 2012

General Manager (Signature)

SATRA
TECHNOLOGY

Issued to:

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

Notified Body: 2777

SATRA customer number: P1720

EL) Type-Examination Certificate

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

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

Product reference:

Clear- 697024575 XXX
Yellow-697024575 XXX
Blue-697024575 XXX
White-697024575 XXX

Description:

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

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

Classification:

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

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

Technical reports/Approval documents:
SGS: CH:TX:7420016049, CH:TX:7420016055,QDHL17030039870T, QDHL17030039880T, CH:TX: 9420028491-1, CH:TX:9420028490, CH:TX: 1042061966, CH:TX: 1042059408
SATRA: CHT0272448/1814. CHT0285339/1921, CHT0280247/1903

[redacted]

Anita Brennan

Jacque Glasspool

TÜ[redacted]

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:

[redacted]

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 f[redacted]and on behalf of SATRA Technology Europe Limited

Dated: 5th March 2020

This certificate is valid until: *March 2021*

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/11804-01/E00-00	697024575 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

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

[redacted]

INDICATIONS FOR USE

Applicant: [redacted]

510(k) Number: Kll。"幻

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

Indications of Use:

A patient examination glove is a disposable device intended tor medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (2ICFR 880.6250)

Prescription Use_____ Over the Counter Use X

Factory Initials _____

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

5lO(k)Number： *kHoNbi*

INTCO
英科医疗

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

EU DECLARATION OF CONFORMITY

Manufacturer

Na [redacted]
Co., Ltd.
[redacted]

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10, le Vcrd 2595AA, The Netherlands

Declares that the MDR described hereafter

Product name and model:

Disposable Vinyl (PVC) Gloves

Authorized Represenlalive

UMDNScode： 11882

UDI-DI: 6970245751019 / 6970245751026 / 6970245751033 / 6970245751040

6970245751057

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

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

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

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

I he above mentioned declaration of contbnnily is exclusively under the responsibility of

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

Place, date

[redacted]19-05-06 Chi Yongtao P!ant manager

Legally binding signature. Function