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

PSB Singapore

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

SUBJECT:

Testing of Disposable Nitrile Glove submitted by
[redacted] Medical Products Co., Ltd. on 18 Feb 2019.

TESTED FOR:

[redacted] Medical Products Co., Ltd
g Road
y 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

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

[redacted]CAL PRODUCTS CO., LTD
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

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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

[redacted]UCTS CO., LTD
[redacted]RY 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
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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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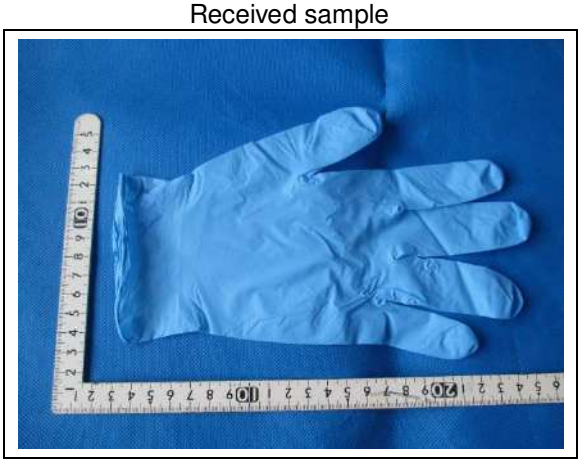
Sample Photo:

Received sample



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[redacted]AL PRODUCTS CO., LTD
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

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)

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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.

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)

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End of Report

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TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

[redacted]Co., Ltd.
No [redacted]Block F,
[redacted]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 60079[redacted]

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60079[redacted]
Report No.: 15044656[redacted]

Organization: [redacted]o., Ltd.
[redacted]lock F,
[redacted]ng 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 Zertifizierungsstelle

X. Ren

Date: 2012-11-13

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Doc. 2/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 600794[redacted]
Report No.: 15044656[redacted]

Organization: [redacted]s Co., Ltd.
[redacted]9, Block F,
[redacted] 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
TÜVRheinland®
Zertifizierungsstelle

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 6007[redacted]
Report No.: 1504465[redacted]

Organization: [redacted], Ltd.
[redacted]ck F,
[redacted] 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

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

X. Ren

Date: 2012-11-13

Compliance Report

Applicant: [redacted] Products Co., Ltd.
Address: Qilu Chemical Industry Park, Zibo City, Shandong Province, China

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

Product Classification: 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 test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

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

General Manager (Signature)

Issued to: [redacted]oducts Co. Ltd
[redacted]dustrial Park
Qingzhou
Shandong
262506
China

Notified Body: 2777

SATRA customer number: P1720

EU Type-Examination Certificate

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

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

Product reference:

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

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
10 XL	225	235	205	215

Classification:

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

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

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

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

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

Expiry date: 06/08/2023

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]al Products Co Ltd
an Industrial Park
ou
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
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

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: [redacted] 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

INTCO
英科医疗

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

EU DECLARATION OF CONFORMITY

Manufacturer

[redacted]Medical Products

oad, Naoshan
hou, Shandong,
China

Authorized Representative

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

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

Declares that the MDR described hereafter

Product name and model:

Disposable Vinyl（PVC）Gloves

UMDNS code：11882

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

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

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

CE

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

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

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

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

Shandong 2019-05-06

Place , date

Chi Yongtao Plant manager

Legally binding signature, Function