
MORLIGNE
XCYILIAO
Nitrile & Latex Gloves Producer
Medical & PPE gloves supplies from china

XCYILIAO MORLIGNE

AGENDA

1. COMPANIES PROFILE
2. PRODUCTION FACILITIES
3. LATEX GLOVES
4. NITRILE GLOVES
5. OUR CLIENTS
6. CONTACT US

COMPANIES PROFILE

XCYILIAO

For over 10 years, XCYILIAO has managed to supply medical devices and PPE at the right price on a global level. In 2020, XCYILIAO & MORLIGNE took the initiative of investing in nitrile and latex glove production lines in order to answer the emerging demand due to the Covid-19 pandemic. Today, our company has over 100 production lines in 15 different sites located in China.

MORLIGNE

For over 10 years, XCYILIAO has managed to supply medical devices and PPE at the right price on a global level. In 2020, XCYILIAO & MORLIGNE took the initiative of investing in nitrile and latex glove production lines in order to answer the emerging demand due to the Covid-19 pandemic. Today, our company has over 100 production lines in 15 different sites located in China.

PARTNERSHIP

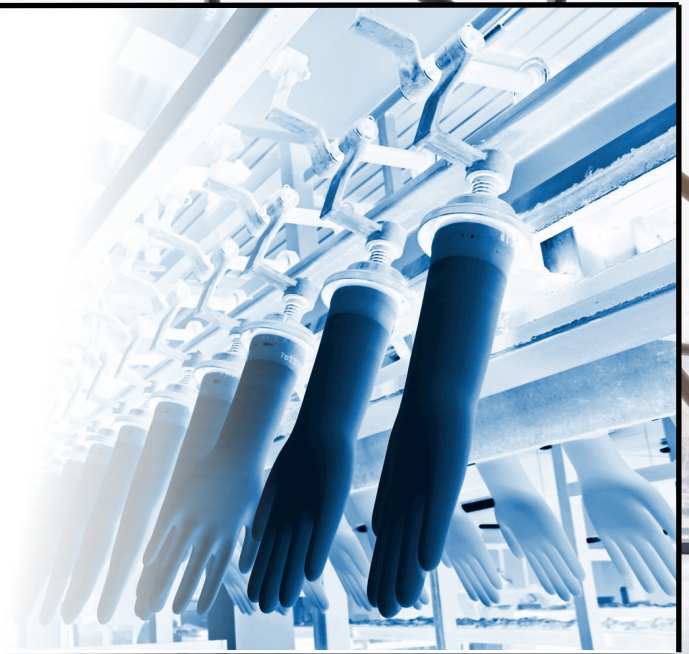
In 2020, XCYILIAO & MORLIGNE took the initiative of investing in nitrile and latex glove production lines in order to answer the emerging demand due to the Covid-19 pandemic

(Left: Mr. Yin, CEO & Partner at XCYILIAO.
Right: Mr. Rajraji: CEO & Founder at Morligne

XCYILIAO MORLIGNE

PRODUCTION FACILITIESc

- 8 factories in Guangdong Province
- 4 Warehouse in Guangdong Province
- 2 factories in Henan Province
- Total: 148 production flexible production lines for Nitrile and Latex production
- 122 People on board




广东星灿兄弟医疗科技有限公司
ISO9001:2008质量体系认证及高新技术企业


XCYILIAO
星灿医疗


XCYILIAO
星灿医疗
Disposable Gloves
100 Pcs/Box | 10 Boxes/Carton
Carton:36x24.5x25.5cm
N.W.:
G.W.:
QTY: 1000 PCS


XCYILIAO
星灿医疗

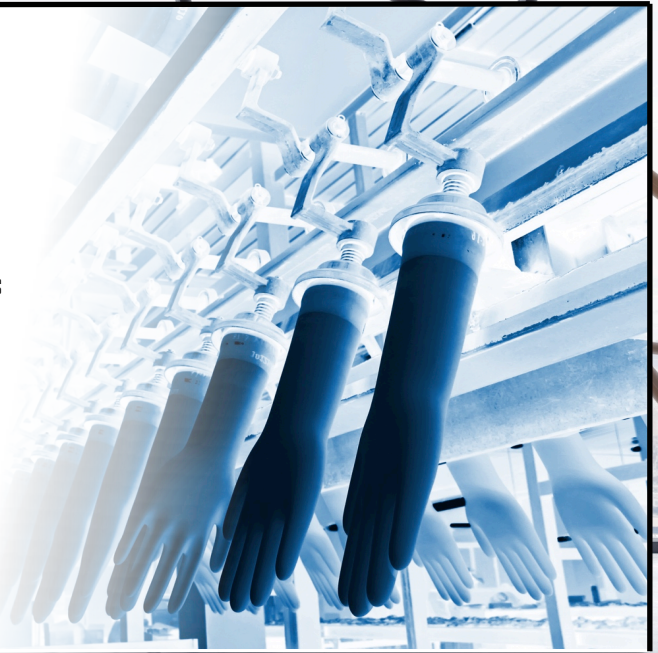
XCYILIAO MORLIGNE

OUR PRODUCT LINES

Our solutions cover both medical and Civil (PPE) standards

NITRILE GLOVES (POWER-FREE)
Medical and Civil CE/FDA Certified
100pcs/box

LATEX GLOVES
Medical and Civil CE/FDA Certified
100pcs/box



XCYILIAO

MORLIGNE

NITRILE

LATEX

	NITRILE	LATEX
Chemical resistant	✪✪✪	✪✪
Comfort / Elasticity	✪✪	✪✪✪
Sensitivity	✪✪	✪✪✪
Protection from Allergies	✪✪	✖
Biodegradability	✪	✪✪✪
Cost effective	✪	✪✪

XCYILIAO MORLIGNE

DATA SHEET.

型号 Model	XS	S	M	L	XL	公差 Tolerance
重量 （克/只） Weight (g/piece)	3.2	3.8	4.2	4.5	5	±0.5
长度 (mm) Length (mm)	240	240	240	240	240	±1
掌部宽度 (mm) Length width (mm)	>75	>80	>90	>100	>110	±5
袖口厚度 (mm) Cuff thickness (mm)	0.06					±0.02
掌心厚度 (mm) Palm thickness (mm)	0.07					±0.02
指部厚度 (mm) Finger thickness (mm)	0.11					±0.03
拉伸强度 (mm) Tensile strength (mm)	老化前和老化后，不低于1.9兆帕 Before and after aging, not less than 1.9 MPa					
色差 Chromatic aberration	3种 3species					
常规包装方式：100只/盒 10h盒/箱 Regular packing： 100 pcs/box 10box/ctn						


LATEX GLOVES.
MEDICAL & PPE MULTIFUNCTIONNAL
LATEX GLOVES.
CE
FDA
RoHS

XCYILIAO MORLIGNE

A Cost-effective And Highly Biodegradeble Solution

Latex Gloves (Medical & PPE Grade Certified)

Made from organic rubber, latex gloves are a processed agriculture product. Assured flexibility and elasticity. These gloves are used as personal protective equipment preventing contamination in medical facilities and areas.

- Powder Free Latex Gloves.
- Super tactile sensitivity.
- Ultimate comfort and fit.
- Each batch tested with AQL 1.4 standards.
- Superior medical grade, confortable fit.
- Multi-functional applications (medical, civil and professional).
- Available in S, M ,L and XL.

XCYILIAO

LATEX POWDER FREE GLOVES

100 GLOVES I 1 BOX

Comfortable Nitrile free gloves with textured fingertips

- Medical standards •
- PPE grade certified •
- Single usage •
- Non sterile •
- Latex free •
- Powder free •

XCYILIAO

Produced with the higest quality materials

Supple and • robust

XCYILIAO

Snug and long-lasting

Our nitrile gloves provide great stretching proprieties materials with no ripping or tearing.

XCYILIAO

You won't even realize you're wearing gloves!

With a thickness of 2.5ml, our gloves are thinner than 99% of gloves you can find on the market. Approved by tattoo artists!

Great sensitivity and touchscreen friendly. You can wear your gloves under all circumstances.

XCYILIAO

Size references

This chart is but a guideline. Different materials, styles and thickness will have a different fit.

Hand width

GLOVE Size	Inches	mm
S	2.9-3.3	77-85
M	3.3-3.7	85-96
L	3.7-4.2	96-108
XL	4.2-4.6	108-115

XCYILIAO

Biodegradable

Bury it in soil, after 10 months, GLOVES will disappear, to FEED BACK earth.

XCYILIAO

Applications

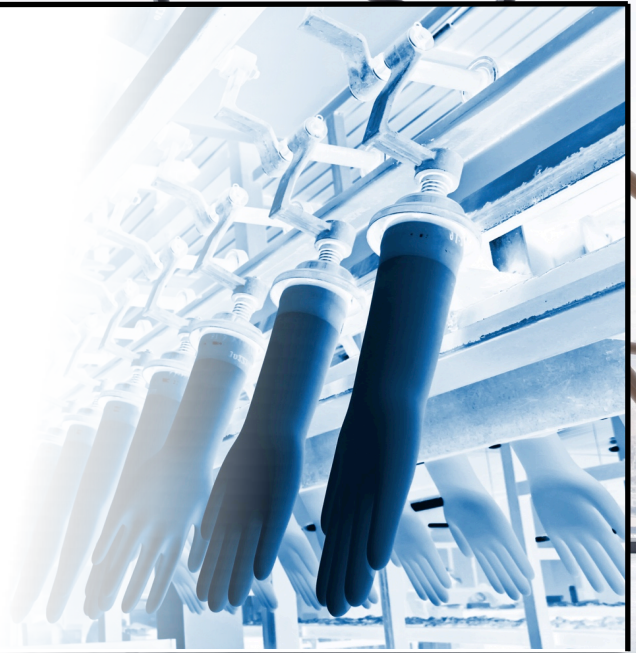
Multi-function and wide use, anytime and anywhere to care for your hands.

- Tattoo artists
- Medical
- Automotive
- Electronic applications
- Janitorial
- Painting
- Parts handling
- Hair salons

XCYILIAO MORLIGNE

CERTIFICATION LIST

- GB-31604 (CIVIL) ✔
- EN455 (Medical) ✔
- ROHS ✔
- GB10213-2006 ✔
- FDA ✔
- CE - MEDICAL DEVICES ✔



NTEK北测

201819122458

检测报告 Test Report

报告编号 Report No.: DGF200817056KD04 Page 1 of 5

申请商 Applicant	:	广东星灿兄弟医疗科技有限公司 GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd
地址 Address	:	广州市天河区花城大道 667 号 1303 房 Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou

以下的检测样品及样品信息由客户提供并确认:
The following sample(s) was/were submitted and identified on behalf of the client as:

产品名称 Product Name	:	一次性乳胶手套 / Disposable latex gloves
制造商 Manufacturer	:	广东星灿兄弟医疗科技有限公司 GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd
地址 Address	:	广州市天河区花城大道 667 号 1303 房 Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou
样品接收日期 Date of Sample Received	:	2020-08-17
检测日期 Test period	:	2020-08-17 至 2020-08-21

检测要求 Test requested

依据GB 4806.11-2016 食品安全国家标准 食品接触用橡胶材料及制品
In accordance with GB 4806.11-2016 National Food Safety Standard of Food contact rubber materials and products.

检测方法 Test method : 请参见下一页 Please refer to next page.

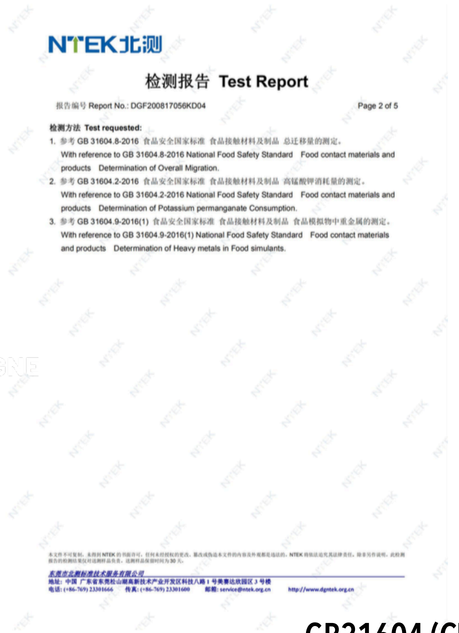
检测结果 Test results : 请参见下一页 Please refer to next page.

主检 Tested by: 张志 (高级工程师) (Senior Engineer) 何毅锟 (主管) (Supervisor)

签发 Approved by: (技术负责人) (Technical director) 日期 Date: 2020-08-21

检测专用章

东莞市北测标准技术服务有限公司
地址: 中国 广东省东莞松山湖高新技术产业开发区科技八路 1 号美赛达欣园区 3 号楼
电话: (+86-769) 23301666 传真: (+86-769) 23301600 邮箱: service@ntek.org.cn http://www.dgntek.org.cn



NTEK北测

检测报告 Test Report

报告编号 Report No.: DGF200817056KD04 Page 2 of 5

检测方法 Test requested:

1. 参考 GB 31604.8-2016 食品安全国家标准 食品接触材料及制品 总迁移量的测定。
   With reference to GB 31604.8-2016 National Food Safety Standard Food contact materials and products Determination of Overall Migration.
2. 参考 GB 31604.2-2016 食品安全国家标准 食品接触材料及制品 高锰酸钾消耗量的测定。
   With reference to GB 31604.2-2016 National Food Safety Standard Food contact materials and products Determination of Potassium permanganate Consumption.
3. 参考 GB 31604.9-2016(1) 食品安全国家标准 食品接触材料及制品 食品模拟物中重金属的测定。
   With reference to GB 31604.9-2016(1) National Food Safety Standard Food contact materials and products Determination of Heavy metals in Food simulants.

东莞市北测标准技术服务有限公司
地址: 中国 广东省东莞松山湖高新技术产业开发区科技八路 1 号美赛达欣园区 3 号楼
电话: (+86-769) 23301666 传真: (+86-769) 23301600 邮箱: service@ntek.org.cn http://www.dgntek.org.cn

XCYILIAO MORLIGNE

GB31604 (CIVIL STANDARD)

NTEK北测

检测报告 Test Report

报告编号 Report No.: DGF200817056KD04

申请商 Applicant	: 广东星灿兄弟医疗科技有限公司 : GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd
地址 Address	: 广州市天河区花城大道 667 号 1303 房 : Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou

以下的检测样品及样品信息由客户提供并确认:
The following sample(s) was/were submitted and identified on behalf of the client as:

产品名称 Product Name	: 一次性乳胶手套 / Disposable latex gloves
制造商 Manufacturer	: 广东星灿兄弟医疗科技有限公司 : GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd
地址 Address	: 广州市天河区花城大道 667 号 1303 房 : Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou
样品接收日期 Date of Sample Received	: 2020-08-17
检测日期 Test period	: 2020-08-17 至 2020-08-21

检测要求 Test requested
依据GB 4806.11-2016 食品安全国家标准 食品接触用橡胶材料及制品
In accordance with GB 4806.11-2016 National Food Safety Standard of Food contact rubber materials and products.

检测方法 Test method : 请参见下一页 Please refer to next page.

检测结果 Test results : 请参见下一页 Please refer to next page.

主检 Tested by: 张志 (高级工程师) (Senior Engineer)

审核 Reviewed by: 何颖锟 (主管) (Supervisor)

签发 Approved by: (技术负责人) (Technical director)

Date: 2020-08-21

NTEK北测

检测报告 Test Report

报告编号 Report No.: DGF200817056KD04

检测方法 Test requested:

1. 参考 GB 31604.8-2016 食品安全国家标准 食品接触材料及制品 总迁移量的测定。
   With reference to GB 31604.8-2016 National Food Safety Standard Food contact materials and products Determination of Overall Migration.
2. 参考 GB 31604.2-2016 食品安全国家标准 食品接触材料及制品 高锰酸钾消耗量的测定。
   With reference to GB 31604.2-2016 National Food Safety Standard Food contact materials and products Determination of Potassium permanganate Consumption.
3. 参考 GB 31604.9-2016(1) 食品安全国家标准 食品接触材料及制品 食品模拟物中重金属的测定。
   With reference to GB 31604.9-2016(1) National Food Safety Standard Food contact materials and products Determination of Heavy metals in Food simulants.

NTEK北测

检测报告 Test Report

报告编号 Report No.: DGF200817056KD04

检测结果 Test results:

检测项目 Test Items		单位 Unit	限值 Limit	结果 Results No.1
感官测试* Sensory test*		---	色泽正常,无异臭、污物。迁移试验所得浸泡液不应有着色、浑浊、沉淀、异臭等感官性的劣变。Colour and lustre should be normal and without smell and dirt. The soak solution should be colorless, no turbidity, precipitation and smell after overall migration test.	色泽正常，无异臭、污物。迁移试验所得浸泡液无着色、浑浊、沉淀、异臭等感官性的劣变。Colour and lustre is normal and without smell and dirt. The soak solution is colorless, and has no turbidity, precipitation and smell after overall migration test.
总迁移量 Overall migration	20%乙醇 20% ethanol, 40℃, 0.5h	mg/dm²	≤10	<3.0
	50%乙醇 50% ethanol, 40℃, 0.5h	mg/dm²	≤10	4.9
高锰酸钾消耗量 Potassium permanganate consumption	水 Water, 60℃, 0.5h	mg/kg	≤10	3.5
重金属(以 Pb 计) Heavy metal (Pb)	4%乙酸 4% acetic acid, 60℃, 0.5h	mg/kg	≤1.0	<1.0
结论 Conclusion				通过 Pass

XCYILIAO MORLIGNE

GB31604 (CIVIL STANDARD)

NTEK北测

检测报告 Test Report

报告编号 Report No.: DGF200817056KD04 Page 4 of 5

检测部位描述 Test Part Description:

No.1: 白色乳胶 White latex

备 注 Note:

(1) mg/dm²=毫克每平方分米 milligram per square decimeter; mg/kg=ppm=0.0001%;

(2) ≤=小于或等于 less than or equal; <=小于 less than;

(3) "—"=不适用 not conducted;

(4) "*" : 该项目只在 CNAS 的认可范围内，不在 CMA 的认可范围内，不作为国内社会公正性证明数据；
"*" : This project is within the scope of CNAS certifiate and not within CMA, which does not serve as a certification in society;

(5) 报告中的英文内容是参考中文内容的译本，中英文内容如有歧异，概以中文内容为准。
The English content in the report is based on the translation of the Chinese content. If there is any discrepancy between the Chinese and English content, the Chinese content shall prevail.

东莞市北测标准技术服务有限公司
地址：中国 广东省东莞松山湖高新技术产业开发区科技八路 1 号奥德达科园区 3 号楼
电话：(+86-769) 23301666 传真：(+86-769) 23301600 邮箱：service@ntek.org.cn http://www.dgntek.org.cn

NTEK北测

检测报告 Test Report

报告编号 Report No.: DGF200817056KD04 Page 5 of 5

样品照片 Photograph of Sample:

报告完 End of Report

本文件不可复制。未得到 NTEK 的书面许可，任何未经授权的更改、篡改或伪造本文件的内容及外观都是违法的。NTEK 将依法追究其法律责任。除非另作说明，此检测报告的检测结果仅对送测样品负责。送测样品保留时间为 30 天。

东莞市北测标准技术服务有限公司
地址：中国 广东省东莞松山湖高新技术产业开发区科技八路 1 号奥德达科园区 3 号楼
电话：(+86-769) 23301666 传真：(+86-769) 23301600 邮箱：service@ntek.org.cn http://www.dgntek.org.cn

GB31604 (CIVIL STANDARD)

XCYILIAO MORLIGNE

SGS

Test Report No. SZXEC2100291201 Date: 04 Feb 2021

GUANGDONG XINGCANXIONGDI MEDICAL TECHNOLOGY CO., LTD
ROOM B10, FOURTH FLOOR, NO. 137 (PLANT A1), PACIFIC INDUSTRIAL ZONE, XINTANG TOWN, ZENGCHENG DISTRICT, GUANGZHOU

The following sample(s) was/were submitted and identified on behalf of the clients as : Disposable latex gloves

SGS Job No. :	RP21-001969 - SZ
Date of Sample Received :	01 Feb 2021
Testing Period :	01 Feb 2021 - 04 Feb 2021
Test Requested :	Selected test(s) as requested by client.
Test Method :	Please refer to next page(s).
Test Results :	Please refer to next page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Shenzhen Branch

Andy Ni
Approved Signatory

Member of the SGS Group (SGS SA)

SGS

Test Report No. SZXEC2100291201 Date: 04 Feb 2021

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description
SN1	SZX21-002912.001	White material

Remarks :
(1) 1 mg/kg = 1 ppm = 0.0001%
(2) MDL = Method Detection Limit
(3) ND = Not Detected (< MDL)
(4) "-" = Not Regulated

Elemental analysis, Hexavalent Chromium(Cr(VI)), Flame Retardants, Phthalates

Test Method : With reference to IEC 62321-4:2013+AMD1:2017, IEC62321-5:2013, IEC62321-7-2:2017, IEC 62321-6:2015 and IEC62321-8:2017, analyzed by ICP-OES, UV-Vis and GC-MS.

Test Item(s)	Limit	Unit	MDL	001
Cadmium (Cd)	100	mg/kg	2	ND
Lead (Pb)	1,000	mg/kg	2	ND
Mercury (Hg)	1,000	mg/kg	2	ND
Hexavalent Chromium (Cr(VI))	1,000	mg/kg	8	ND
Sum of PBBs	1,000	mg/kg	-	ND
Monobromobiphenyl	-	mg/kg	5	ND
Dibromobiphenyl	-	mg/kg	5	ND
Tribromobiphenyl	-	mg/kg	5	ND
Tetrabromobiphenyl	-	mg/kg	5	ND
Pentabromobiphenyl	-	mg/kg	5	ND
Hexabromobiphenyl	-	mg/kg	5	ND
Heptabromobiphenyl	-	mg/kg	5	ND
Octabromobiphenyl	-	mg/kg	5	ND
Nonabromobiphenyl	-	mg/kg	5	ND
Decabromobiphenyl	-	mg/kg	5	ND
Sum of PBDEs	1,000	mg/kg	-	ND
Monobromodiphenyl ether	-	mg/kg	5	ND
Dibromodiphenyl ether	-	mg/kg	5	ND
Tribromodiphenyl ether	-	mg/kg	5	ND
Tetrabromodiphenyl ether	-	mg/kg	5	ND
Pentabromodiphenyl ether	-	mg/kg	5	ND

Member of the SGS Group (SGS SA)

SGS

Test Report No. SZXEC2100291201 Date: 04 Feb 2021

Test Item(s)	Limit	Unit	MDL	001
Hexabromodiphenyl ether	-	mg/kg	5	ND
Heptabromodiphenyl ether	-	mg/kg	5	ND
Octabromodiphenyl ether	-	mg/kg	5	ND
Nonabromodiphenyl ether	-	mg/kg	5	ND
Decabromodiphenyl ether	-	mg/kg	5	ND
Dibutyl Phthalate (DBP)	1000	mg/kg	50	ND
Butyl benzyl Phthalate (BBP)	1000	mg/kg	50	ND
Bis(2-ethylhexyl) Phthalate (DEHP)	1000	mg/kg	50	ND
Diisobutyl Phthalate (DIBP)	1000	mg/kg	50	ND

Remark: The limit(s) was/were submitted by applicant.

Member of the SGS Group (SGS SA)

ROHS

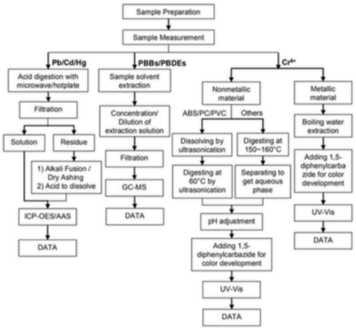
SGS

Test Report No. SZXEC2100291201 Date: 04 Feb 2021 Page 4 of 6

ATTACHMENTS

Pb/Cd/Hg/Cr6+/PBBs/PBDEs Testing Flow Chart

1) These samples were dissolved totally by pre-conditioning method according to below flow chart. (Cr^{6+} and PBBs/PBDEs test method excluded).



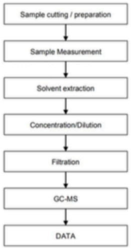
Member of the SGS Group (SGS SA)

SGS

Test Report No. SZXEC2100291201 Date: 04 Feb 2021 Page 5 of 6

ATTACHMENTS

Phthalates Testing Flow Chart

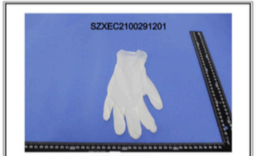


Member of the SGS Group (SGS SA)

SGS

Test Report No. SZXEC2100291201 Date: 04 Feb 2021 Page 6 of 6

Sample photo:



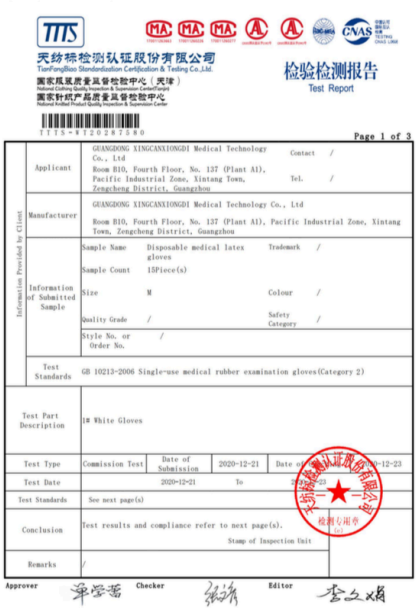
SZX21-002912.001

SGS authenticate the photo on original report only

*** End of Report ***

Member of the SGS Group (SGS SA)

ROHS



天纺标检测认证股份有限公司
TianFangBiao Standardization Certification & Testing Co.,Ltd.
国家服装质量监督检验中心（天津）
国家针织产品质量监督检验中心

检验检测报告
Test Report

TTTS-WT20287580

Page 1 of 3

Information Provided by Client	Applicant	GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd Room B10, Fourth Floor, No. 137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District, Guangzhou	Contact / Tel. /	
	Manufacturer	GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd Room B10, Fourth Floor, No. 137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District, Guangzhou		
	Information of Submitted Sample	Sample Name: Disposable medical latex gloves Sample Count: 18Piece(s) Size: M Quality Grade: / Style No. or Order No.: /	Trademark: / Colour: / Safety Category: /	
	Test Standards	GB 10213-2006 Single-use medical rubber examination gloves(Category 2)		
Test Part Description		1# White Gloves		
Test Type	Commission Test	Date of Submission: 2020-12-21	Date of [illegible]: 2020-12-23	
Test Date	2020-12-21 To [illegible]			
Test Standards	See next page(s)			
Conclusion	Test results and compliance refer to next page(s). Stamp of Inspection Unit			
Remarks	/			

Approver [illegible] Checker [illegible] Editor [illegible]

天纺标检测认证股份有限公司
TianFangBiao Standardization Certification & Testing Co.,Ltd.
国家服装质量监督检验中心（天津）
国家针织产品质量监督检验中心

检验检测报告
Test Report

TTTS-WT20287580

Page 2 of 3

Test Items	Description	Unit	Standard Requirement	Results	Conclusions	Test Method/ Remarks
1# White Gloves						
Watertightness Test	/	/	As per standard requirement	No penetration	Pass	GB 10213-2006
Tensile Properties	Minimum Force at break before accelerated ageing	N	7.0	7.0	Pass	ISO 37:2017 ISO 188:2011
	Minimum Elongation at break before accelerated ageing	%	500	500		

GB10213-2006 (MEDICAL STANDARD)

XCYILIAO MORLIGNE

SGS ilac-MRA CNAS TESTING CNAS L0604

scan to see the report

QDHL2103501048MD

Test Report

Report No.: QDHL2103501048MD

Sample Description:	MEDICAL LATEX EXAMINATION GLOVES
Applicant:	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.
Test Type:	SUBMITTED BY CLIENT

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

Page 1 of 6

SGS ilac-MRA CNAS TESTING CNAS L0604

Report No.: QDHL2103501048MD

Test Report

Sample information	Sample Description	MEDICAL LATEX EXAMINATION GLOVES	Color	WHITE
	Received sample quantity/ Tested sample quantity	20PCS/ 5PCS	Type/ Specifications	NOT PROVIDED
	Lot No.	20201125	Lot Quantity	NOT PROVIDED
	Manufacture Date	2020-11-25	Expiration Date	3 YEARS
	Material/Appearance	LATEX	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	NOT PROVIDED		
Client information	Applicant	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.		
	Applicant address	B10, FOURTH FLOOR, NO.137 (PLANT A1), PACIFIC INDUSTRIAL ZONE, XINTANG TOWN, ZENGCHENG DISTRICT, GUANGZHOU.		

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

Page 2 of 6

SGS ilac-MRA CNAS TESTING CNAS L0604

Report No.: QDHL2103501048MD

Test information	Sample Receiving Date	MAR.23,2021	Test Period Date	MAR.23,2021 TO MAR.29,2021
	Sample No.	QDHL2103501048MD (CZHL2103001090MD)	Test environment	Meet requirement
	Test items	Removable surface powder		
	Testing Accordance	EN 455-3:2015 Medical Gloves for Single Use–Part 3: Requirements and Testing for Biological Evaluation clause 4.4		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: MAR.29,2021			
Remark	/			

Approver: Date: MAR.29,2021

Auditor: Date: MAR.29,2021

Compiler: Lillian Diao Date: MAR.29,2021

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

Page 3 of 6

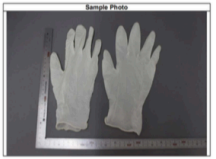
EN455 (MEDICAL STANDARD)

XCYILIAO MORLIGNE

SGS

Report No.: QDHL2103501048MD

Sample Photo



SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 4 of 6

SGS

Report No.: QDHL2103501048MD

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Removable surface powder	mg	EN 455-3: 2015 Clause 5.2 EN ISO 21171: 2006 Method B	Sample quantity: 5pcs Average: ≤2	0.2	Pass

Remarks:

1. Finishes of gloves: Powder-free gloves (As per client's requirement).
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

End of Report

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 5 of 6

SGS

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; altered;a copy without the red testing seal of SGS.
2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.
3. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.
4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.
5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address:
SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

Tel: 0532-68999187 Zip: 266101
Fax: 0532-80991952

E-mail: Emily.Zhang@sgs.com

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 6 of 6

EN455 (MEDICAL STANDARD)

Fiscal Year 2021

Certificate of Registration

This certifies that GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD

B10, Fourth Floor, No. 137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District,

Guangzhou, Guangdong, 511300, CHINA

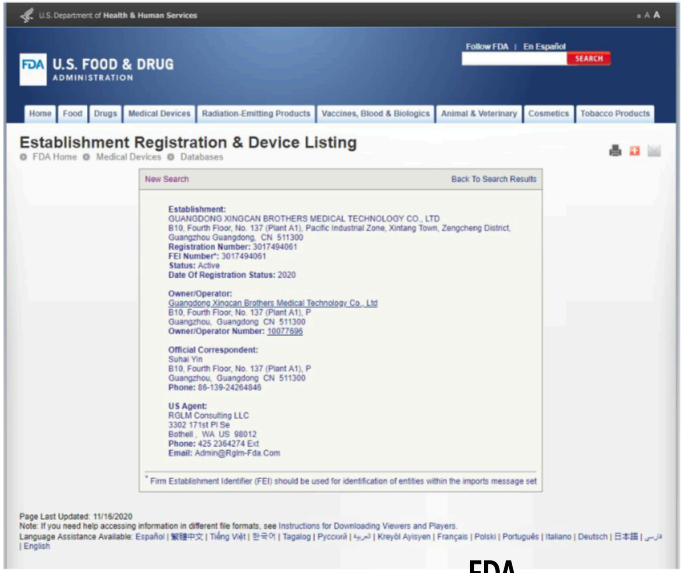
has completed the United States Food and Drug Administration (FDA) medical device registration and listing, pursuant to Part 807, Code of Federal Regulations Title 21 for FY 2021. RGLM consulting has confirmed the registration and listing are currently effective on the date as listed below.

Registration /Owner Operate Number	3017494061
Product Code	LYU
Regulation Number	878.4040
Effective Date of Registration	September 30, 2021
Device Classification Name	ACCESSORY, SURGICAL APPAREL
Device Proprietary Name	Disposable Medical Nitrile gloves,Disposable Medical vinyl gloves,Disposable Medical Mix Nitrile gloves,Disposable Medical latex gloves, Disposable vinyl gloves,Disposable Nitrile Gloves,Disposable mixed nitrile gloves,Disposable latex gloves

This certificate affirms that the above establishment and product(s) are currently registered with U.S. Food and Drug Administration (FDA). This registration and listing will remain effective until the end of Year 2021, unless the establishment terminates the registration and/or product listing. RGLM consulting or this certificate does not make any representations or warranties to denote endorsement or approval of the establishment or its products. RGLM consulting assumes no liability to any person or entity in connection with the foregoing. FDA does not issue or recognize this certificate. RGLM Consulting is not affiliated with the U.S. Food and Drug Administration.

Roy Zhang/ President
RGLM Consulting
admin@rglm-fda.com
United States of America
www.rglm-FDA.com

Seal 2018



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

New Search | Back To Search Results

Establishment:
GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD
B10, Fourth Floor, No. 137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District,
Guangzhou Guangdong, CN 511300
Registration Number: 3017494061
FEI Number*: 3017494061
Status: Active
Date Of Registration Status: 2020

Owner/Operator:
Guangdong Xingcan Brothers Medical Technology Co., Ltd
B10, Fourth Floor, No. 137 (Plant A1), P
Guangzhou, Guangdong CN 511300
Owner/Operator Number: 10077996

Official Correspondent:
Suhai Yin
B10, Fourth Floor, No. 137 (Plant A1), P
Guangzhou, Guangdong CN 511300
Phone: 86-139-24264846

US Agent:
RGLM Consulting LLC
3302 171st Pl Se
Bothell, WA US 98012
Phone: 425 2364274 Ext
Email: Admin@Rglm-Fda Com

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 11/16/2020
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/09022021.7

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Guangdong Xingcan Brothers Medical Technology Co., Ltd.
B10, Fourth Floor, No.137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District, Guangzhou

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/269/2021**

CE

Issued on: 09/02/2021

Valid until: 08/02/2022

Authorized Signatory
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com

EC REP CERTIFICATE

ANNEX I Medical Device Products

Medical Nitrile Examination Gloves

Medical Vinyl Examination Gloves

Medical Latex Examination Gloves

Medical Vinyl/Nitrile blended Gloves

CE

www.cmcmedicaldevices.com

CE - MECIAL DEVICES

AGREEMENT EC REP
CMC MEDICAL DEVICES 200301

This Agreement made on February 02, 2021 between **Guangdong Xingcan Brothers Medical Technology Co., Ltd.** Located in **B10, Fourth Floor, No.137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District, Guangzhou.** (hereinafter referred to as "COMPANY") and **M/s CMC Medical Devices & Drugs S.L.** located in C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain (hereinafter referred to as "Authorized Representative")

Have agreed as follows with regard to the handling of all products (hereinafter called "Products") manufactured by Company and sold to EU in order to comply to the requirements set out in the COUNCIL DIRECTIVE 93/42/EEC Concerning Medical Devices (MDD), Regulation (EU) 2017/745 or 98/79/EC, Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices (as per applicability) and latest version of "Guidelines on a Medical Devices Vigilance System".

Appointment
Company hereby appoints Authorized Representative, who accepts such appointment, as a representative for the "Business Area" and "Product Categories" set out in Appendix A. The responsibility of both parties is as stated hereafter. Service of European Authorized Representative cover the MDD 93/42/EEC or 98/79/EEC. The service will cover the new Regulation (EU) 2017/745 and (EU)2017/746 on medical devices and in vitro diagnostic when this regulation take effect.

Claim Handling
Authorized Representative shall notify company about any received claims and any change of laws and regulations related to company's products set out in Appendix A. Company is the immediate responsible person for the claim handling and regulation compliance.

Accident Handling
On receiving information of an incident (accident), as defined in the MDD 93/42/EEC, Regulation (EU) 2017/745 or 98/79/EC, Regulation (EU) 2017/746 (as per applicability) and MEDDEV 2.12-1 "Guidelines on a Medical Devices Vigilance System", the following procedures shall be applied:

Authorized Representative shall notify occurrence of an incident in its business area to Company immediately upon receiving of incident.
Upon receiving information of any incident Company shall perform the necessary analysis of the situation immediately and send the incident report to Authorized Representative according to the requirements of latest version of "Guidelines on a Medical Devices Vigilance System". In that way Authorized Representative can submit the report

to the relevant Competent Authority as defined in the timescale of latest version of "Guidelines on a Medical Devices Vigilance System".

If applicable, based on the report Company shall instruct Authorized Representative of the necessary countermeasures to be taken. Authorized Representative shall inform the relevant Competent Authority and customer as required in the countermeasure plan issued by Company.

Responsibilities on Technical Documentation:

i. Company shall establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity for the "Product Categories" set out in Appendix A to be able to comply with the MDD and MDR requirements.
ii. Company shall transfer the agreed Technical Documentation and Declaration of Conformity to Authorized Representative upon request.
iii. Company shall have the responsibility to provide to Authorized Representative any additional documentation as required by the Competent Authority or Notified Body.
iv. The authorized representative shall provide a copy of this agreement to the competent authority, upon request.

Instruction Manual (If applicable)
Company shall be responsible for the content of instruction (user's) manuals, and shall ensure that English language instruction manuals are available to Authorized Representative. Company shall ensure that the required local language instruction manuals are provided to the customers.

Registration

The Authorized Representative shall register or notify the products set out in Appendix A to the Competent Authority of the member state in which he has his registered place of business.

Company shall have all data allowing for identification of concerned devices together with the label and the instruction for use available to authorized representative upon request by competent authority.

Tasks to be performed by Authorized Representative:
i. Verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the company;
ii. Keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and

supplements, available for the competent authorities for a period of at least 10 years after the last device covered by the eu declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market;
iii. Comply with the registration obligations laid down in article 31 of MDR/2017/745 OR art 28 of MDR /2017/746 and verify that the company has complied with the registration obligations laid down in articles 27 and 29 MDR/2017/745 OR art 24 and 26 of MDR/2017/746;
iv. In response to a request from a competent authority, provide that the competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official union language determined by the member state concerned.
v. Forward to the company any request by a competent authority of the member state in which the authorized representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;
vi. Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
vii. Terminate this agreement if the company acts contrary to its obligations under this regulation;
viii. Authorized representatives will have permanently and continuously at their disposal at least one person responsible for regulatory compliance (PRRC) who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.

Obligations of Manufacturer Company:

i. COMPANY must comply with all the requirements specified in Article 10 MDR - Regulation 2017/745 or art 10 MDR 746/2017 regarding general obligations of manufacturers.
ii. COMPANY shall procure and maintain at all times during the term of this Agreement a Product liability insurance covering the products placed on the European market. This liability insurance should include "EAR" as well. This insurance, however, will not protect "EAR" against liability which results from its unauthorized Activities, wrongful or negligent acts of omission, or breach of this Agreement.
This agreement will not be valid if the manufacturer does not meet this requirement.

Other Obligations of Authorized Representative & Company:

i. The authorized representative shall provide all documentation and information that a market surveillance authority may require for the purpose of market surveillance.
ii. The authorized representatives shall rescind his contract with the company if the latter does not provide him with the access to the necessary information.
iii. Company shall keep authorized representative informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning paragraphs a) to c) hereunder shall be informed.

a) Safeguard Clause

i. "Where a Member State ascertains that any of the medical devices specified in Appendix A, when correctly used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service." If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such measures to the company and advise the company as to the implications of this decision.
ii. When the Commission finds that national measures taken under the Safeguard Clause "are unjustified, it shall immediately so inform the Member State which took the measures and the company or authorized representative". If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.

b) Vigilance

i. In case of an incident and If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.
ii. The company should ensure that the involved authorized representative is kept informed of incident reports and Field Safety Corrective Actions.

c) Serious adverse events during clinical investigation, i.e. in the premarket phase

i. According to Article 80 of MDR 745/2017 and art 76 of 746/2017, "all serious adverse events must be fully recorded and immediately notified to all Competent Authorities of the Member States in which the clinical investigation is being performed by the sponsor".
ii. Authorized representative should inform the company of decisions of a Member State in respect of refusal or restriction of the placing the devices specified in Appendix A in the market.

(Appendix A): (product list)

Medical Nitrile Examination Gloves
Medical Vinyl Examination Gloves
Medical Latex Examination Gloves
Medical Vinyl/Nitrile blended Gloves

The following countries represent Authorized Representative's Business Area:

EUROPEAN COMMUNITY TERRITORY

Annual Fee:

Validity of Agreement : This agreement shall stand valid up to **February 01, 2022**. The Company shall apply for renewal of the agreement at least 30 days prior to expiry of this agreement.

Guangdong Xinyicai Brothers Medical Technology Co., Ltd. (COMPANY)

Authorized Signatory

Country on February 02, 2021.

CMC MEDICAL DEVICES & DRUGS S.L.
(EC REP AUTHORIZED REPRESENTATIVE)

Authorized Signatory

Spain on February 02, 2021.

NITRILE GLOVES.

MEDICAL & PPE MULTIFUNCTIONNAL NITRILE GLOVES.

XCYILIAO

NITRILE POWDER FREE GLOVES

100 GLOVES I 1 BOX

Comfortable Nitrile free gloves with textured fingertips

- Medical standards
- PPE grade certified
- Single usage
- Non sterile
- Latex free
- Powder free

XCYILIAO

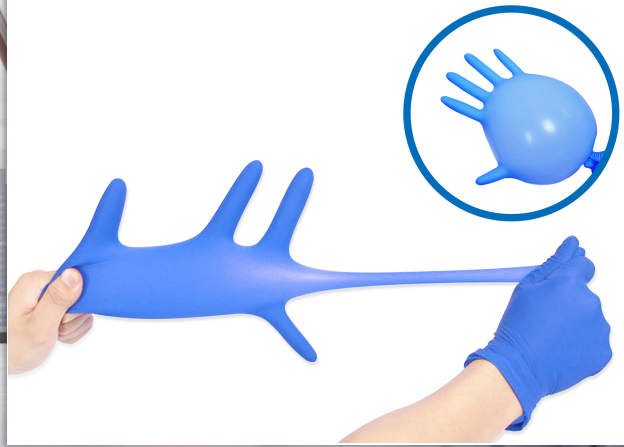
Produced with the higest quality materials

- Supple and robust

XCYILIAO

Snug and long-lasting

Our nitrile gloves provide great stretching proprieties materials with no ripping or tearing.



XCYILIAO

You won't even realize you're wearing gloves!

With a thickness of 2.5ml, our gloves are thinner than 99% of gloves you can find on the market. Approved by tattoo artists!

Great sensitivity and touchscreen friendly. You can wear your gloves under all circumstances.

XCYILIAO

Size references

This chart is but a guideline. Different materials, styles and thickness will have a different fit.

GLOVE Size	Inches	mm
S	2.9-3.3	77-85
M	3.3-3.7	85-96
L	3.7-4.2	96-108
XL	4.2-4.6	108-115

Hand width

XCYILIAO

Against allergies

No irritability no side affects.
Safe materials that ensure your hand´s safety and comfort.

XCYILIAO

Applications

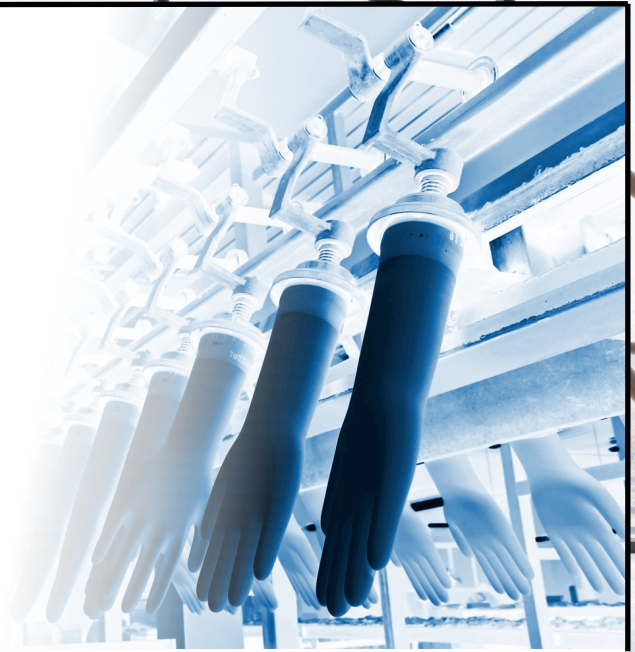
Multi-function and wide use, anytime and anywhere to care for your hands.

- Janitorial
- Painting
- Automotive
- Electronic applications
- Tattoo artists
- Medical
- Parts handling
- Hair salons

XCYILIAO MORLIGNE

CERTIFICATION LIST

- GB-31604 (CIVIL) ✔
- EU1935/2004/EC ✔
- ROHS ✔
- REACH ✔
- FDA ✔
- GB10213-2006 ✔
- EN3741-2-3-4-5 ✔
- EN455 (Medical) ✔
- ASTM ✔
- CE - MEDICAL DEVICES ✔



NTEK北测

检测报告 Test Report

报告编号 Report No.: DGF200817056KD02 Page 1 of 4

申 请 者 Applicant : 广东星烛兄弟医疗科技有限公司 / GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd

地 址 Address : 广州市天河区花城大道 667 号 1303 房 / Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou

以下的检测样品及样品信息由客户提供并确认:
The following sample(s) was/were submitted and identified on behalf of the client as:

产品名称 Product Name : 一次性丁腈手套 / Disposable Nitrile Gloves

制 造 商 Manufacturer : 广东星烛兄弟医疗科技有限公司 / GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd

地 址 Address : 广州市天河区花城大道 667 号 1303 房 / Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou

样品接收日期 Date of Sample Received : 2020-08-17

检测日期 Test period : 2020-08-17 至 2020-08-27

检测要求 Test requested

依据GB 4806.11-2016 食品安全国家标准 食品接触用橡胶材料及制品
In accordance with GB 4806.11-2016 National Food Safety Standard of Food contact rubber materials and products.

检测方法 Test method : 请参见下一页 Please refer to next page.

检测结果 Test results : 请参见下一页 Please refer to next page.

主 检 Tested by: 张志 (高级工程师) (Senior Engineer)

何毅强 (主管) (Supervisor)

签 发 Approved by: 2020-08-27 (技术负责人) (Technical director)

检测专用章

NTEK北测

检测报告 Test Report

报告编号 Report No.: DGF200817056KD02 Page 2 of 4

检测方法 Test requested:

1. 参考 GB 31604.8-2016 食品安全国家标准 食品接触材料及制品 总迁移量的测定。
With reference to GB 31604.8-2016 National Food Safety Standard Food contact materials and products Determination of Overall Migration.
2. 参考 GB 31604.2-2016 食品安全国家标准 食品接触材料及制品 高锰酸钾消耗量的测定。
With reference to GB 31604.2-2016 National Food Safety Standard Food contact materials and products Determination of Potassium permanganate Consumption.
3. 参考 GB 31604.9-2016(1) 食品安全国家标准 食品接触材料及制品 食品模拟物中重金属的测定。
With reference to GB 31604.9-2016(1) National Food Safety Standard Food contact materials and products Determination of Heavy metals in Food simulants.

GB31604 (CIVIL STANDARD)

NTEK北测

检测报告 Test Report

检测结果 Test results:

检测项目 Test Items		单位 Unit	限值 Limit	结果 Results No.1
感官测试* Sensory test*		---	色泽正常,无异臭,污物。迁移试验所得浸泡液不应有着色、浑浊、沉淀、异臭等感官性的劣变。 Colour and lustre should be normal and without smell and dirt. The soak solution should be colorless, no turbidity, precipitation and smell after overall migration test.	色泽正常，无异臭、污物。迁移试验所得浸泡液无着色、浑浊、沉淀、异臭等感官性的劣变。 Colour and lustre is normal and without smell and dirt. The soak solution is colorless, and has no turbidity, precipitation and smell after overall migration test.
总迁移量 Overall migration	20%乙醇 20% ethanol, 40℃, 0.5h	mg/dm^2	≤10	<3.0
	50%乙醇 50% ethanol, 40℃, 0.5h	mg/dm^2	≤10	8.1
高锰酸钾消耗量 Potassium permanganate consumption	水 Water, 60℃, 0.5h	mg/kg	≤10	7.9
重金属(以 Pb 计) Heavy metal (Pb)	4%乙酸 4% acetic acid, 60℃, 0.5h	mg/kg	≤1.0	<1.0
结论 Conclusion				通过 Pass

NTEK北测

检测报告 Test Report

检测部位描述 Test Part Description:

No.1: 蓝色丁腈 Blue nitrile

备 注 Note:

(1) mg/dm^2=毫克每平方分米 milligram per square decimeter; mg/kg=ppm=0.0001%;

(2) ≤=小于或等于 less than or equal; <=小于 less than;

(3) "---"=不适用 not conducted;

(4) "*"：该项目只在 CNAS 的认可范围内，不在 CMA 的认可范围内，不作为国内社会公正性证明数据；
"*": This project is within the scope of CNAS certifiate and not within CMA, which does not serve as a certification in society;

(5) 报告中的英文内容是参考中文内容的译本，中英文内容如有歧异，概以中文内容为准。
The English content in the report is based on the translation of the Chinese content. If there is any discrepancy between the Chinese and English content, the Chinese content shall prevail.

样品照片 Photograph of Sample:

报告完 End of Report

GB31604 (CIVIL STANDARD)

XCYILIAO MORLIGNE

NTEK北测

Test Report

Report No.: DGC200902012KE02 Page 1 of 4

Applicant : GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd
Address : Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou

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

Product Name : Disposable Nitrile Gloves
Model : /
Manufacturer : GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd
Address : Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou

Date of Sample Received : Sept. 02, 2020
Test period : Sept. 02, 22020 - Sept. 07, 2020

Test requested : In accordance with California Proposition 65, to determine the Phthalates (DEHP, DBP, BBP, DnHP, DIDP, DINP) and the total Lead content on submitted sample.

Test method : Please refer to next page.

Test result : Please refer to next page.

Tested by: George Zhang (Senior Engineer)
Reviewed by: Tammy He (Supervisor)
Approved by: Caby Yang (Technical director) **Date:** Sept. 07, 2020

Dongguan NTEK Testing Technology Co., Ltd.
Address: Building 3, Metasilicon Park, Keji 8th Road, Songshan Lake High-Tech Industrial Development Zone, Dongguan, Guangdong, China
Tel: (+86-769) 22301666 Fax: (+86-769) 22301680 Email: service@ntek.org.cn http://www.dgntek.org.cn

NTEK北测

Test Report

Report No.: DGC200902012KE02 Page 2 of 4

Test results:

1.Total Lead content :

Test Item	Test method	Unit	MDL	Result No.1
Total Lead (Pb)	With reference to CPSC-CH-E1002-08.3, tested by ICP-OES.	mg/kg	2	N.D.

2. Phthalates content:

Test Items	Test method	Unit	MDL	Results No.1	Conclusion
Di-n-hexyl phthalate (DnHP)	With reference to CPSC-CH-C1001-09.4, tested by GC-MS	mg/kg	30	N.D.	Pass
Di (2-ethyl hexyl)-phthalate (DEHP)		mg/kg	30	N.D.	Pass
Diisodecyl phthalate (DIDP)#		mg/kg	100	N.D.	Pass
Butylbenzyl phthalate (BBP)		mg/kg	30	N.D.	Pass
Dibutuyl phthalate (DBP)		mg/kg	30	N.D.	Pass
Diisononyl phthalate (DINP)		mg/kg	100	N.D.	---

Test Part Description:

No.1: Blue nitrile gloves

Note:

(1) mg/kg=ppm=0.0001%;
(2) N.D.=Not Detected (<MDL);
(3) MDL=Method Detection Limit;
(4) California Proposition 65 - Phthalates in Vinyl gloves
According to CGC-08-473477: DEHP, BBP, DBP, DIDP, DnHP content in the product shall not exceed 600ppm (0.06%);
(5) The client declares that the product can be use in children's products.
(6) "#" means that CNAS accredited projects does not include this item or this method.

Dongguan NTEK Testing Technology Co., Ltd.
Address: Building 3, Metasilicon Park, Keji 8th Road, Songshan Lake High-Tech Industrial Development Zone, Dongguan, Guangdong, China
Tel: (+86-769) 22301666 Fax: (+86-769) 22301680 Email: service@ntek.org.cn http://www.dgntek.org.cn

CALIFORNIA, PROPOSITION 65

XCYILIAO MORLIGNE

NTEK北测 Test Report

Report No.: DGC200902012KE02 Page 3 of 4

Operation Flow Chart:

1. To Determine Lead:

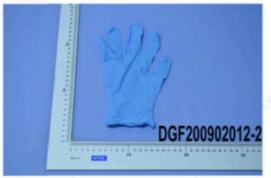
2. To Determine Phthalates:

Dongguan NTEK Testing Technology Co., Ltd.
Address: Building 3, Metasilicon Park, Keji 8th Road, Songshan Lake High-Tech Industrial Development Zone, Dongguan, Guangdong, China
Tel: (+86-769) 23301666 Fax: (+86-769) 23301600 Email: service@ntek.org.cn http://www.dgntek.org.cn

NTEK北测 Test Report

Report No.: DGC200902012KE02 Page 4 of 4

Photograph of Sample:



End of Report

Dongguan NTEK Testing Technology Co., Ltd.
Address: Building 3, Metasilicon Park, Keji 8th Road, Songshan Lake High-Tech Industrial Development Zone, Dongguan, Guangdong, China
Tel: (+86-769) 23301666 Fax: (+86-769) 23301600 Email: service@ntek.org.cn http://www.dgntek.org.cn

CALIFORNIA, PROPOSITION 65

NTEK北测 **Test Report**

Report No.: DGF200902012KE08 Page 1 of 3

Applicant : GUANGDONG XINGCANXINGDI Medical Technology Co., Ltd
Address : Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou

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

Product Name : Disposable Nitrile Gloves
Model : /
Manufacturer : GUANGDONG XINGCANXINGDI Medical Technology Co., Ltd
Address : Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou

Date of Sample Received : Sept. 02, 2020
Test period : Sept. 02, 2020 - Sept. 08, 2020

Test requested: **Conclusion:**

For material which contact with foodstuff, selected tests were performed for compliant with the following regulations:
-Regulation 1935/2004/EC on materials and articles intended to come into contact with food; Pass
-API2004)5 Testing of Rubber.

Test method : Please refer to next page.

Test result : Please refer to next page.

Tested by: George Zhang (Senior Engineer) Tammy He (Supervisor)

Approved by: Caby Yang (Technical director) **Date:** Sept. 08, 2020

Dongguan NTEK Testing Technology Co., Ltd.
Address: Building 3, Metasilicon Park, Keji 8th Road, Songshan Lake High-Tech Industrial Development Zone, Dongguan, Guangdong, China
Tel: (+86-769) 22898666 Fax: (+86-769) 22898688 Email: service@ntek.org.cn http://www.dgntek.org.cn

NTEK北测 **Test Report**

Report No.: DGF200902012KE08 Page 2 of 3

Test Results:

1. Overall Migration test:
Method: With reference to
BS EN 1186-1:2002 for selection of conditions and test methods;
BS EN 1186-3:2002 aqueous food simulants by total immersion method;
EN 1186-14:2002 for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs using test media iso-octane and 95 % ethanol".

Test conditions	Unit	Limit	Results No.1	Conclusion
Overall migration in 20% ethanol, 40℃, 0.5h	mg/dm²	10	3.75	Pass
Overall migration in 95% ethanol, 40℃, 0.5h	mg/dm²	10	<3.0	Pass
Overall migration in iso-octane, 20℃, 0.5h	mg/dm²	10	<3.0	Pass

2. N-nitrosamines and N-nitrosatable substances test (Unit : mg/kg):
Method: With reference to EN 12868:2017*, determined by GC-MS.

Test Item	Test conditions	Limit	MDL	Result No.1	Conclusion
N-nitrosamines	Artificial saliva 40℃, 24h	0.01	0.01	N.D.	Pass
N-nitrosatable substances	Artificial saliva 40℃, 24h	0.1	0.1	N.D.	Pass

Test Part Description:
No.1: Blue nitrile

Dongguan NTEK Testing Technology Co., Ltd.
Address: Building 3, Metasilicon Park, Keji 8th Road, Songshan Lake High-Tech Industrial Development Zone, Dongguan, Guangdong, China
Tel: (+86-769) 22898666 Fax: (+86-769) 22898688 Email: service@ntek.org.cn http://www.dgntek.org.cn

NTEK北测 **Test Report**

Report No.: DGF200902012KE08 Page 3 of 3

Note:
(1) mg/dm² = milligram per square decimeter;
(2) mg/kg=ppm=0.0001%;
(3) N.D.=Not Detected(<MDL);
(4) MDL=Method Detection Limit;
(5) < = less than;
(6) "*" means that CNAS accredited projects does not include this item.

Photographs of Samples:

Tested sample

End of Report

Dongguan NTEK Testing Technology Co., Ltd.
Address: Building 3, Metasilicon Park, Keji 8th Road, Songshan Lake High-Tech Industrial Development Zone, Dongguan, Guangdong, China
Tel: (+86-769) 22898666 Fax: (+86-769) 22898688 Email: service@ntek.org.cn http://www.dgntek.org.cn

EU1935/2004/EC

XCYILIAO MORLIGNE

NTEK北测

Test Report

Report No.: DGF200902012KE06 Page 1 of 2

Applicant : GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd
Address : Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou

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

Product Name : Disposable Nitrile Gloves
Model : /
Manufacturer : GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd
Address : Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou

Date of Sample Received : Sept. 02, 2020
Test period : Sept. 02, 2020 - Sept. 08, 2020

Test requested:
For material which contact with foodstuff, selected tests were performed for compliant with the regulations US Food and Drug Administration (FDA).

Conclusion:
Pass

Test method : With reference to FDA 21 CFR 177.2600 Rubber articles intended for repeated use.

Test result : Please refer to next page.

Tested by: George Zhang (Senior Engineer)
Reviewed by: Tammy He (Supervisor)
Approved by: Caby Yang (Technical director) Sept. 08, 2020

NTEK Testing Technology Co., Ltd. Report Seal

Dongguan NTEK Testing Technology Co., Ltd.
Address: Building 3, Meisuidaxin Park, Keji 8th Road, Songshan Lake High-Tech Industrial Development Zone, Dongguan, Guangdong, China
Tel: (+86-769) 22301666 Fax: (+86-769) 22301680 Email: service@ntek.org.cn http://www.dgntek.org.cn

NTEK北测

Test Report

Report No.: DGF200902012KE06 Page 2 of 2

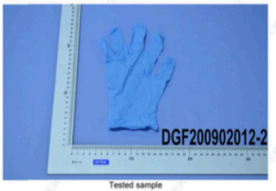
Test Results:

Test Items	Test conditions	Unit	Limit	Results No.1	Conclusion
Maximum extractable fraction in distilled water	Reflux temperature, the first 7 h	mg/in.^{2}	20	<3.0	Pass
	Reflux temperature, the following 2h	mg/in.^{2}	1	0.5	Pass
Maximum extractable fraction in n-hexane	Reflux temperature, the first 7 h	mg/in.^{2}	175	<50	Pass
	Reflux temperature, the following 2h	mg/in.^{2}	4	<1.0	Pass

Test Part Description:
No.1: Blue nitrile

Note: mg/in.^{2} = milligram per square inch

Photographs of Sample:



Tested sample

End of Report

Dongguan NTEK Testing Technology Co., Ltd.
Address: Building 3, Meisuidaxin Park, Keji 8th Road, Songshan Lake High-Tech Industrial Development Zone, Dongguan, Guangdong, China
Tel: (+86-769) 22301666 Fax: (+86-769) 22301680 Email: service@ntek.org.cn http://www.dgntek.org.cn

FDA

XCYILIAO MORLIGNE

Test Report

（2020） WSZ FHL NO.F0994

Product Name Disposable Nitrile Gloves

Client GUANGDONG XINGCANXIONGDI Medical Technology Co.,Ltd

Manufacturer GUANGDONG XINGCANXIONGDI Medical Technology Co.,Ltd

Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co.,Ltd.

Test Report

[2020] WSZ FHL NO.F0994 Page 1 of 2

Product name	Disposable Nitrile Gloves	Specification	—
		Brand	—
Client/Add/Tel	GUANGDONG XINGCANXIONGDI Medical Technology Co.,Ltd/Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou/13790202600		
Manufacturer/ Add/Tel	GUANGDONG XINGCANXIONGDI Medical Technology Co.,Ltd/Room 1303, 667 Huacheng Avenue, Tianhe District, Guangzhou/13790202600		
Sample grade	—	Sample number	GW F0994-2020
Sample quantity	20 pcs	Receiving date of sample	09/09/2020
Test type	Entrusted inspection	Article number/Batch number/Style number	—
Test date	11/09/2020	Testing sites	Testing room
Sample state	Meeting the requirements of testing	Sample description	Blue
Test standard(s)	EN 374-2:2014 Protective gloves against dangerous chemicals and micro-organisms Part 2: Determination of resistance to penetration		
Test items	Air leak test, water leak test		
Test result	The detail of test results see on Page 2.		
Note	For the entrusted sample test, the technical responsibilities are undertaken for the test results of the supplied samples only.		

Issue date: 11/09/2020

Approver: Reviewer: Chief Tester:

Test Result

[2020] WSZ FHL NO.F0994 Page 2 of 2

S.No.	Test item	Unit	Technical requirements	Test result		Single item decision
1	Air leak test	—	—	Sample 1	No bubbles escape	—
				Sample 2	No bubbles escape	
				Sample 3	No bubbles escape	
				Sample 4	No bubbles escape	
2	Water leak test	—	—	After the addition of water: Sample 1	No leakage	—
				Sample 2	No leakage	
				Sample 3	No leakage	
				Sample 4	No leakage	
				2 min after the initial addition of water: Sample 1	No leakage	
				Sample 2	No leakage	
				Sample 3	No leakage	
				Sample 4	No leakage	
Note						

The End

EN374-2

SGS

Test Report No. CANEC2014939802 Date: 01 Sep 2020 Page 1 of 6

GUANGDONG XINGCANXIONGDI MEDICAL TECHNOLOGY CO., LTD
ROOM 1303, 667 HUACHENG AVENUE, TIANHE DISTRICT, GUANGZHOU

The following sample(s) was/were submitted and identified on behalf of the clients as : Disposable Nitrile Gloves

SGS Job No. :	CP20-045203 - SZ
Date of Sample Received :	27 Aug 2020
Testing Period :	27 Aug 2020 - 01 Sep 2020
Test Requested :	Selected test(s) as requested by client.
Test Method :	Please refer to next page(s).
Test Results :	Please refer to next page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Violet Shi
Violet.Shi
Approved Signatory

SGS

Test Report No. CANEC2014939802 Date: 01 Sep 2020 Page 2 of 6

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description
SN1	CAN20-149398.002	Blue material

Remarks :

(1) 1 mg/kg = 1 ppm = 0.0001%
(2) MDL = Method Detection Limit
(3) ND = Not Detected (< MDL)
(4) "-" = Not Regulated

Elemental analysis, Hexavalent Chromium(Cr(VI)), Flame Retardants, Phthalates

Test Method : With reference to IEC 62321-4:2013+A1:2017, IEC 62321-5:2013, IEC 62321-7-2:2017 , IEC 62321-6:2015 and IEC 62321-8:2017, analyzed by ICP-OES , UV-Vis and GC-MS .

Test Item(s)	Limit	Unit	MDL	002
Cadmium (Cd)	100	mg/kg	2	ND
Lead (Pb)	1,000	mg/kg	2	ND
Mercury (Hg)	1,000	mg/kg	2	ND
Hexavalent Chromium (Cr(VI))	1,000	mg/kg	8	ND
Sum of PBBs	1,000	mg/kg	-	ND
Monobromobiphenyl	-	mg/kg	5	ND
Dibromobiphenyl	-	mg/kg	5	ND
Tribromobiphenyl	-	mg/kg	5	ND
Tetrabromobiphenyl	-	mg/kg	5	ND
Pentabromobiphenyl	-	mg/kg	5	ND
Hexabromobiphenyl	-	mg/kg	5	ND
Heptabromobiphenyl	-	mg/kg	5	ND
Octabromobiphenyl	-	mg/kg	5	ND
Nonabromobiphenyl	-	mg/kg	5	ND
Decabromobiphenyl	-	mg/kg	5	ND
Sum of PBDEs	1,000	mg/kg	-	ND
Monobromodiphenyl ether	-	mg/kg	5	ND
Dibromodiphenyl ether	-	mg/kg	5	ND
Tribromodiphenyl ether	-	mg/kg	5	ND
Tetrabromodiphenyl ether	-	mg/kg	5	ND
Pentabromodiphenyl ether	-	mg/kg	5	ND

SGS

Test Report No. CANEC2014939802 Date: 01 Sep 2020 Page 3 of 6

Test Item(s)	Limit	Unit	MDL	002
Hexabromodiphenyl ether	-	mg/kg	5	ND
Heptabromodiphenyl ether	-	mg/kg	5	ND
Octabromodiphenyl ether	-	mg/kg	5	ND
Nonabromodiphenyl ether	-	mg/kg	5	ND
Decabromodiphenyl ether	-	mg/kg	5	ND
Dibutyl phthalate (DBP)	1,000	mg/kg	50	ND
Butyl benzyl phthalate (BBP)	1,000	mg/kg	50	ND
Bis (2-ethylhexyl) phthalate (DEHP)	1,000	mg/kg	50	ND
Diisobutyl Phthalates (DIBP)	1,000	mg/kg	50	ND

Notes :

The limit(s) was/were submitted by applicant.

ROHS

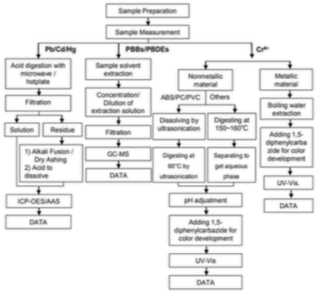
SGS

Test Report No. CANEC2014939802 Date: 01 Sep 2020 Page 4 of 6

ATTACHMENTS

Pb/Cd/Hg/Cr⁶⁺/PBBs/PBDEs Testing Flow Chart

1) These samples were dissolved totally by pre -conditioning method according to below flow chart. (Cr^{6+} and PBBs/PBDEs test method excluded).

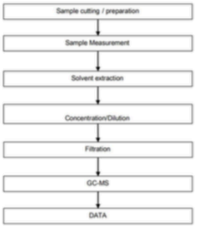


SGS

Test Report No. CANEC2014939802 Date: 01 Sep 2020 Page 5 of 6

ATTACHMENTS

Phthalates Testing Flow Chart



SGS

Test Report No. CANEC2014939802 Date: 01 Sep 2020 Page 6 of 6

Sample photo:

SGS authenticate the photo on original report only

*** End of Report ***

ROHS

XCYILIAO MORLIGNE

TTTS 天纺标检测认证股份有限公司
TianFangBiao Standardization Certification & Testing Co.,Ltd.
国家服装质量监督检验中心（天津）
National Clothing Quality Inspection & Supervision Center(Tianjin)
国家针织产品质量监督检验中心
National Knitted Product Quality Inspection & Supervision Center

检验检测报告
Test Report

TTTS-WT20287594

Information Provided by Client	Applicant	GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd Room B10, Fourth Floor, No. 137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District, Guangzhou		Contact / Tel. /	
	Manufacturer	GUANGDONG XINGCANXIONGDI Medical Technology Co., Ltd Room B10, Fourth Floor, No. 137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District, Guangzhou			
	Information of Submitted Sample	Sample Name	Disposable medical Nitrile Gloves	Trademark	/
		Sample Count	10Piece(s)		
		Size	M	Colour	/
		Quality Grade	/	Safety Category	/
		Style No. or Order No.	/		
	Test Standards	GB 10213-2006 Single-use medical rubber examination gloves(Category 2)			

Test Part Description	1# Blue Gloves				
Test Type	Commission Test	Date of Submission	2020-12-21	Date of	2020-12-23
Test Date	2020-12-21	To	2020-12-23		
Test Standards	See next page(s)				
Conclusion	Test results and compliance refer to next page(s). Stamp of Inspection Unit				
Remarks	/				

Approver Checker Editor

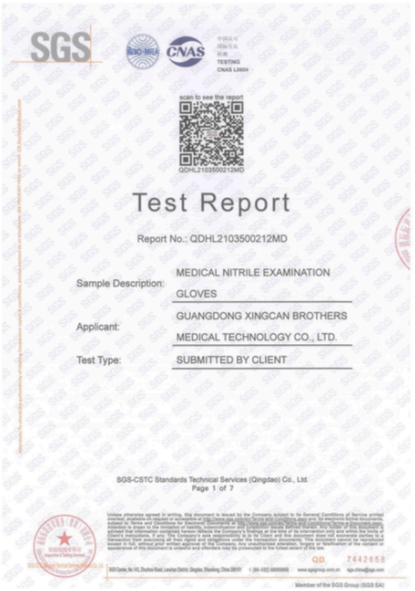
TTTS 天纺标检测认证股份有限公司
TianFangBiao Standardization Certification & Testing Co.,Ltd.
国家服装质量监督检验中心（天津）
National Clothing Quality Inspection & Supervision Center(Tianjin)
国家针织产品质量监督检验中心
National Knitted Product Quality Inspection & Supervision Center

检验检测报告
Test Report

TTTS-WT20287594

Test Items	Description	Unit	Standard Requirement	Results	Conclusions	Test Method/ Remarks
1# Blue Gloves						
Watertightness Test	/	/	As per standard requirement	No penetration	Pass	GB 10213-2006
Tensile Properties	Minimum Force at break before accelerated ageing	N	7.0	7.0	Pass	ISO 37:2017 ISO 188:2011
	Minimum Elongation at break before accelerated ageing	%	500	500		

GB 10213-2006 (MEDICAL)



SGS

scan to see the report

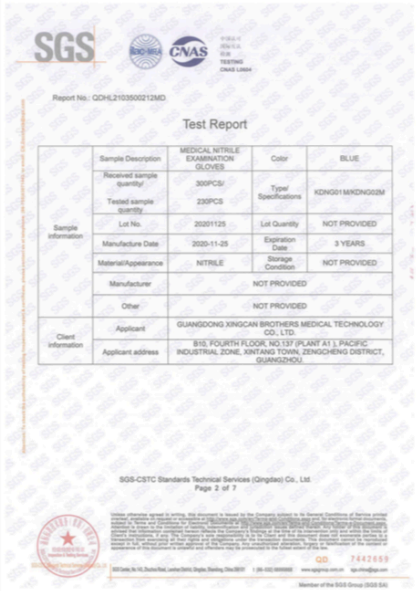
QDHL2103500212MD

Test Report

Report No.: QDHL2103500212MD

Sample Description:	MEDICAL NITRILE EXAMINATION GLOVES
Applicant:	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.
Test Type:	SUBMITTED BY CLIENT

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 1 of 7



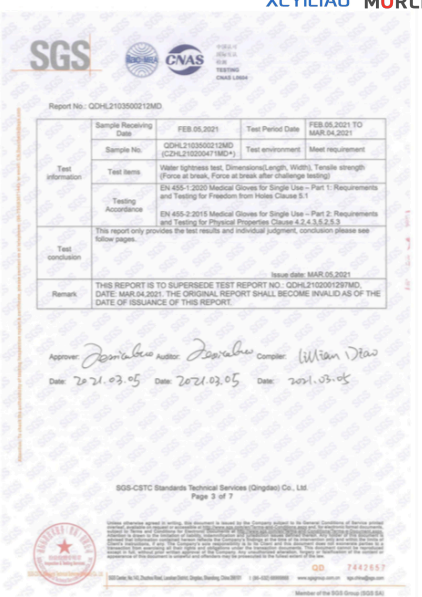
SGS

Report No.: QDHL2103500212MD

Test Report

Sample information	Sample Description	MEDICAL NITRILE EXAMINATION GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	300PCS/ 230PCS	Type/ Specifications	KDNG01MKDNG02M
	Lot No.	20201125	Lot Quantity	NOT PROVIDED
	Manufacture Date	2020-11-25	Expiration Date	3 YEARS
	Material/Appearance	NITRILE	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Other	NOT PROVIDED		
Client information	Applicant	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.		
	Applicant address	B10, FOURTH FLOOR, NO.137 (PLANT A1), PACIFIC INDUSTRIAL ZONE, XINTANG TOWN, ZENGCHENG DISTRICT, GUANGZHOU		

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 2 of 7



SGS

Report No.: QDHL2103500212MD

Test information	Sample Receiving Date	FEB.05,2021	Test Period Date	FEB.05,2021 TO MAR.04,2021
	Sample No.	QDHL2103500212MD (CZHL2102004719MD+1)	Test environment	Meet requirement
	Test Items	Water tightness test, Dimensions(Length, Width), Tensile strength (Force at break, Force at break after challenge testing)		
	Testing Accordance	EN 455-1:2020 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes Clause 5.1 EN 455-2:2015 Medical Gloves for Single Use – Part 2: Requirements and Testing for Physical Properties Clause 4.2,4.3,5.2,5.3		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages.			
			Issue date: MAR.05,2021	
Remark	THIS REPORT IS TO SUPERSEDE TEST REPORT NO.: QDHL2102001297MD, DATE: MAR.04,2021. THE ORIGINAL REPORT SHALL BECOME INVALID AS OF THE DATE OF ISSUANCE OF THIS REPORT.			

Approver: Jasmine Auditor: Jasmine Compiler: Lillian Diao

Date: 2021.03.05 Date: 2021.03.05 Date: 2021.03.05

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 3 of 7

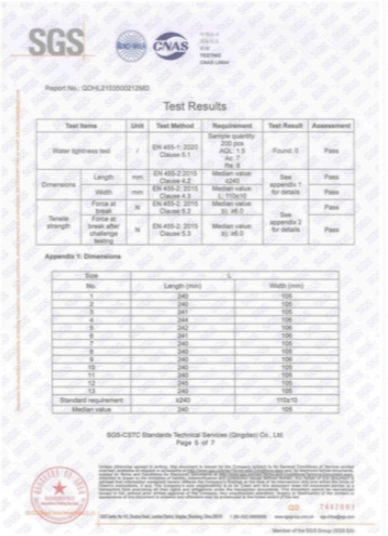
EN455 (MEDICAL)

SGS

Report No.: QDHL2103500212MD

Sample Photo

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 4 of 7



SGS

Report No.: QDHL2103500212MD

Test Results

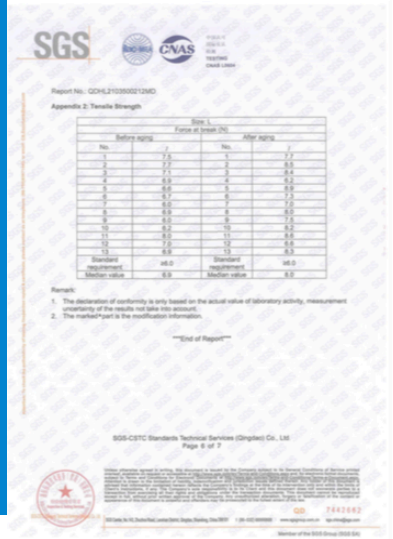
Test Items		Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test		/	EN 455-1: 2020 Clause 5.1	Sample quantity: 2200 pcs AQL: 1.5 Ac: 7 Re: 8	Found: 0	Pass
Dimensions	Length	mm	EN 455-2:2015 Clause 4.2	Median value: ≥240	See appendix 1 for details	Pass
	Width	mm	EN 455-2: 2015 Clause 4.3	Median value: L: 110±10		Pass
Tensile strength	Force at break	N	EN 455-2: 2015 Clause 5.2	Median value: S): ≥6.0	See appendix 2 for details	Pass
	Force at break after challenge testing	N	EN 455-2: 2015 Clause 5.3	Median value: S): ≥6.0		Pass

Appendix 1: Dimensions

Size No.	L	
	Length (mm)	Width (mm)
1	240	105
2	240	105
3	241	105
4	244	106
5	242	104
6	241	104
7	240	105
8	240	105
9	240	106
10	240	105
11	240	105
12	245	105
13	240	105
Standard requirement	≥240	110±10
Median value	240	105

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 5 of 7

EN455 (MEDICAL)



SGS

Report No.: QDHL2103500212MD

Appendix 2: Tensile Strength

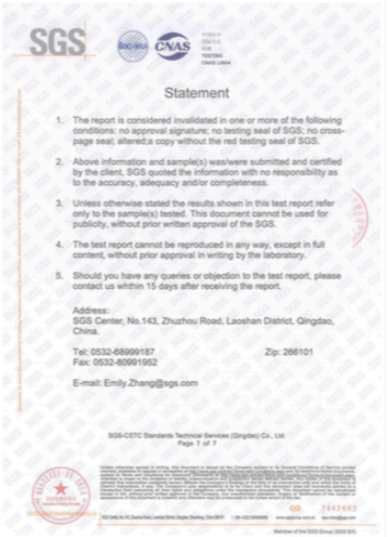
Size: L			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	7.5	1	7.7
2	7.7	2	8.5
3	7.1	3	8.4
4	6.9	4	8.2
5	6.6	5	8.0
6	6.7	6	7.5
7	6.6	7	7.7
8	6.9	8	8.0
9	6.2	9	7.5
10	6.2	10	8.2
11	8.0	11	8.6
12	7.0	12	8.6
13	6.9	13	8.3
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	6.9	Median value	8.0

Remark:

1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
2. The marked*part is the modification information.

****End of Report****

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd
Page 6 of 7



SGS

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; no cross-page seal; altered;a copy without the red testing seal of SGS.
2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.
3. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.
4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.
5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address:
SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

Tel: 0532-68999187 Zip: 266101
Fax: 0532-80991952

E-mail: Emily.Zhang@sgs.com

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd
Page 7 of 7

EN455 (MEDICAL)

SGS CNAS TESTING CNAS L0604

scan to see the report

QDHL2103500644MD

Test Report

Report No.: QDHL2103500644MD

Sample Description:	MEDICAL NITRILE EXAMINATION GLOVES
Applicant:	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO.,LTD.
Test Type:	SUBMITTED BY CLIENT

SGS CNAS TESTING CNAS L0604

Report No.: QDHL2103500644MD

Test Report

Sample information	Sample Description	MEDICAL NITRILE EXAMINATION GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	20PCS/ 5PCS	Type/ Specifications	KDNG01M/ KDNG02M
	Lot No.	20201125	Lot Quantity	NOT PROVIDED
	Manufacture Date	2020-11-25	Expiration Date	3 YEARS
	Material/Appearance	NITRILE	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	NOT PROVIDED		
Client information	Applicant	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO.,LTD.		
	Applicant address	B10, FOURTH FLOOR, NO.137 (PLANT A1), PACIFIC INDUSTRIAL ZONE, XINTANG TOWN, ZENGCHENG DISTRICT, GUANGZHOU.		

SGS CNAS TESTING CNAS L0604

Report No.: QDHL2103500644MD

Test information	Sample Receiving Date	MAR.15,2021	Test Period Date	MAR.15,2021 TO MAR.22,2021
	Sample No.	QDHL2103500644MD	Test environment	Meet requirement
	Test items	Removable surface powder		
	Testing Accordance	EN 455-3:2015 Medical Gloves for Single Use--Part 3: Requirements and Testing for Biological Evaluation Clause 4.4		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: MAR.22,2021			
Remark	/			

Approver: Auditor: Compiler: Lillian Diao

Date: MAR.22,2021 Date: MAR.22,2021 Date: MAR.22,2021

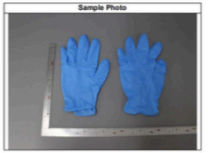
EN455-3 (MEDICAL)

XCYILIAO MORLIGNE

SGS CNAS TESTING CNAS L0604

Report No.: QDHL2103500644MD

Sample Photo



SGS CNAS TESTING CNAS L0604

Report No.: QDHL2103500644MD

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Removable surface powder	mg	EN 455-3: 2015 Clause 5.2 EN ISO 21171: 2006 Method B	Sample quantity: 5pcs Averages2	0.46	Pass

Remarks:

1. Finish of gloves: Powder-free gloves (As per client's requirement).
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

End of Report

SGS CNAS TESTING CNAS L0604

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; altered;a copy without the red testing seal of SGS.
2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.
3. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.
4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.
5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address:
SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

Tel: 0532-68999187 Zip: 266101
Fax: 0532-80991952

E-mail: Emily.Zhang@sgs.com

EN455-3 (MEDICAL)

XCYILIAO MORLIGNE

SGS

scan to see the report

QDHL2104501952SD

Test Report

Report No.: QDHL2104501952SD

Sample Description: DISPOSABLE NITRILE GLOVES

Applicant: GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.

Test Type: SUBMITTED BY CLIENT

SGS

Report No.: QDHL2104501952SD

Test Report

Sample information	Sample Description	DISPOSABLE NITRILE GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	20PCS/ 3PCS	Type/ Specifications	XC101
	Lot No.	20210125	Lot Quantity	NOT PROVIDED
	Manufacture Date	20210125	Expiration Date	20230124
	Material/Appearance	NOT PROVIDED	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	/		
Client information	Applicant	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.		
	Applicant address	B10, FOURTH FLOOR, NO.137 (PLANT A1), PACIFIC INDUSTRIAL ZONE, XINTANG TOWN, ZENGCHENG DISTRICT, GUANGZHOU.		
Test information	Sample Receiving Date	APR.13,2021	Test Period Date	APR.13,2021 TO APR.21,2021
	Sample No.	QDHL2104501952SD	Test environment	Meet requirement
	Test items	Resistance to degradation by chemicals		
	Testing Accordance	EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals Clause 5.3		

SGS

Report No.: QDHL2104501952SD

Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: APR.21,2021
Remark	/

Approver: Auditor: Compiler: Lillian Diao

Date: APR.21,2021 Date: APR.21,2021 Date: APR.21,2021

EN374-1 EN374-4

SGS

Report No.: QDHL210450195 2SD

Sample Photo

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 4 of 6

SGS

Report No.: QDHL210450195 2SD

Test Results

Test Items	Test Method	Requirement	Test Result		Assessment
Resistance to degradation by chemicals	EN ISO 374-1: 2016+A1:2018 Clause 5.3 EN ISO 374-4: 2019	/	Chemical CAS NO.	Sodium hydroxide 40% 1310-73-2	/
			Exposure duration	60min	
			Percentage change in puncture resistance	DR:- 35.05% DR:- 36.25% DR:- 33.71% DR: 35.00% SD: 1.03	
			Observation	No change	

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

End of Report

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 5 of 6

SGS

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; altered;a copy without the red testing seal of SGS.
2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.
3. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.
4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.
5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address: SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.
Tel: 0532-68999187 Zip: 266101 Fax: 0532-80991952
E-mail：Emily.Zhang@sgs.com

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 6 of 6

EN374-1 EN374-4

SGS

Scan to view the report

QDHL210450181 0SD

Test Report

Report No.: QDHL210450181 0SD

Sample Description: DISPOSABLE NITRILE GLOVES

Applicant: GUANGDONG XINGCAN BROTHERS MEDICAL TECNOLOGY CO., LTD.

Test Type: SUBMITTED BY CLIENT

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 1 of 5

SGS

Report No.: QDHL210450181 0SD

Test Report

Sample information	Sample Description	DISPOSABLE NITRILE GLOVES	Color	BLUE
	Received sample quantity	20PCS	Type/ Specifications	XC101
	Lot No.	20210125	Lot Quantity	NOT PROVIDED
	Manufacture Date	20210125	Expiration Date	20230124
	Material/Appearance	NOT PROVIDED	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	/		
Client information	Applicant	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.		
	Applicant address	B10, FOURTH FLOOR, NO.137 (PLANT A1), PACIFIC INDUSTRIAL ZONE, XINTANG TOWN, ZENGCHENG DISTRICT, GUANGZHOU		
Test information	Sample Receiving Date	APR.13,2021	Test Period Date	APR.13,2021 TO APR.21,2021
	Sample No.	QDHL210450181 0SD (TAOHK210170790 1)	Test environment	Meet requirement
	Test items	Glove design and construction-General, Determination of pH value, Polycyclic aromatic hydrocarbons (PAHs), Sizing, Dexterity,		
	Testing Accordance	EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms Part 5: Terminology and performance requirements for micro-organisms risks Clause 5.1		

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 2 of 5

SGS

Report No.: QDHL210450181 0SD

Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: APR.21,2021
Remark	/

Approver: Auditor: Compiler: Lillian Diao

Date: APR.21,2021 Date: APR.21,2021 Date: APR.21,2021

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 3 of 5

SGS

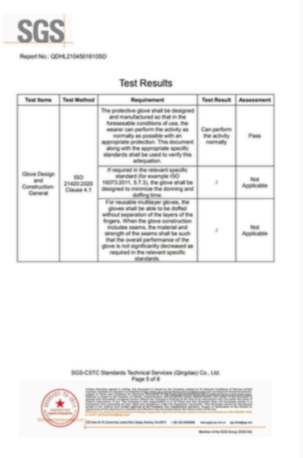
Report No.: QDHL210450181 0SD

Sample Photo

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 4 of 5

EN374-5 EN420

XCYILIAO MORLIGNE

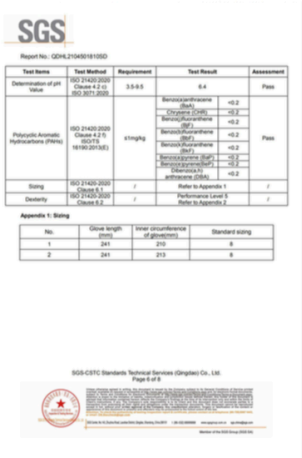


SGS

Report No.: QDHL2104501810SD

Test Results

Test Items	Test Method	Requirement	Test Result	Assessment
Glove Design and Construction-General	ISO 21420:2020 Clause 4.1	The protective glove shall be designed and manufactured so that in the foreseeable conditions of use, the hand can perform the activity for which it is normally as possible with an appropriate protection. This document along with the appropriate specific standards shall be used to verify this adequation.	Can perform the activity normally	Pass
		If required in the relevant specific standard (for example ISO 16073-2:2011, 5.7.3), the glove shall be designed to minimize the donning and doffing time.	/	Not Applicable
		For reusable multilayer gloves, the gloves shall be able to be doffed without separation of the layers of the fingers. When the glove construction is tested according to the relevant test, the strength of the seams shall be such that the overall performance of the glove is not significantly decreased as required in the relevant specific standards.	/	Not Applicable



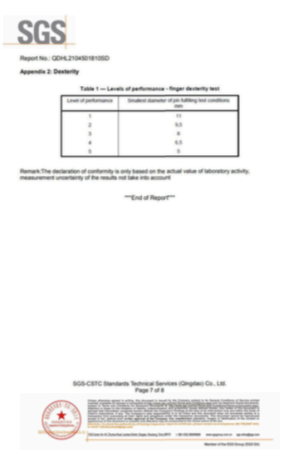
SGS

Report No.: QDHL2104501810SD

Test Items	Test Method	Requirement	Test Result		Assessment
Determination of pH Value	ISO 21420:2020 Clause 4.2 c) ISO 3071:2020	3.5-9.5	6.4		Pass
Polycyclic Aromatic Hydrocarbons (PAHs)	ISO 21420:2020 Clause 4.2 f) ISO/TS 16190:2013(E)	≤1mg/kg	Benzo(a)anthracene (BaA)	<0.2	Pass
			Chrysene (CHR)	<0.2	
			Benzo(b)fluoranthene (BbF)	<0.2	
			Benzo(k)fluoranthene (BkF)	<0.2	
			Benzo(j)fluoranthene (BjF)	<0.2	
			Benzo(a)pyrene (BaP)	<0.2	
			Benzo(e)pyrene(BeP)	<0.2	
			Dibenzo(a,h) anthracene (DBA)	<0.2	
Sizing	ISO 21420:2020 Clause 6.1	/	Refer to Appendix 1		/
Dexterity	ISO 21420:2020 Clause 6.2	/	Performance Level 5 Refer to Appendix 2		/

Appendix 1: Sizing

No.	Glove length (mm)	Inner circumference of glove(mm)	Standard sizing
1	241	210	8
2	241	213	8



SGS

Report No.: QDHL2104501810SD

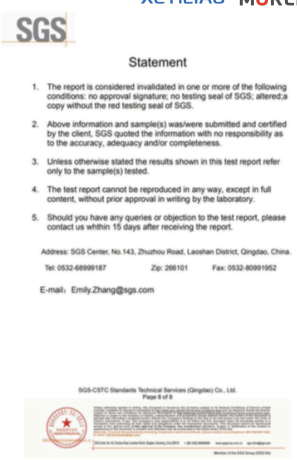
Appendix 2: Dexterity

Table 1 — Levels of performance - finger dexterity test

Level of performance	Smallest diameter of pin fulfilling test conditions (mm)
1	11
2	9,5
3	8
4	6,5
5	5

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

End of Report



SGS

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; altered;a copy without the red testing seal of SGS.
2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.
3. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.
4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.
5. Should you have any queries or objection to the test report, please contact us within 15 days after receiving the report.

Address: SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.
Tel: 0532-68999187 Zip: 266101 Fax: 0532-80991952
E-mail：Emily.Zhang@sgs.com

EN374-5 EN420

XCYILIAO MORLIGNE

SGS

scan it and the report will be verified.

QDHL2104501950SD

Test Report

Report No.: QDHL2104501950SD

Sample Description: DISPOSABLE NITRILE GLOVES

Applicant: GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.

Test Type: SUBMITTED BY CLIENT

SGS

Report No.: QDHL2104501950SD

Test Report

Sample information	Sample Description	DISPOSABLE NITRILE GLOVES	Color	BLUE
	Received sample quantity	20PCS	Type/ Specifications	XC101
	Lot No.	20210125	Lot Quantity	NOT PROVIDED
	Manufacture Date	20210125	Expiration Date	20230124
	Material/Appearance	NOT PROVIDED	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	/		
Client information	Applicant	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.		
	Applicant address	B10, FOURTH FLOOR, NO.137 (PLANT A1), PACIFIC INDUSTRIAL ZONE, XINTANG TOWN, ZENGCHENG DISTRICT, GUANGZHOU.		

SGS

Report No.: QDHL2104501950SD

Test information	Sample Receiving Date	APR.13,2021	Test Period Date	APR.13,2021 TO APR.21,2021
	Sample No.	QDHL2104501950SD	Test environment	Meet requirement
	Test items	Air leak test, Water leak test		
	Testing Accordance	EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms Part 5: Terminology and performance requirements for micro-organisms risks Clause 5.2		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: APR.21,2021			
Remark	/			

Approver: Auditor: Compiler: Lillian Diao

Date: APR.21,2021 Date: APR.21,2021 Date: APR.21,2021

EN374-2

SGS

Report No.: QDHL2104501950SD

Sample Photo

SGS

Report No.: QDHL2104501950SD

Test Results

Test Items	Test Method	Requirement	Test Result		Assessment
Air leak test	EN ISO 374-2: 2019	Air Pressure Used: 2.5KPa. The glove shall not leak.	Sample 1	No bubbles escape	Pass
			Sample 2	No bubbles escape	
			Sample 3	No bubbles escape	
			Sample 4	No bubbles escape	
Water leak test	EN ISO 374-2: 2019	The glove shall not leak.	Sample 1	No leakage	Pass
			Sample 2	No leakage	
			Sample 3	No leakage	
			Sample 4	No leakage	

End of Report

SGS

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; altered;a copy without the red testing seal of SGS.
2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.
3. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.
4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.
5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address: SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

Tel: 0532-68999187 Zip: 266101 Fax: 0532-80991952

E-mail：Emily.Zhang@sgs.com

EN374-2

XCYILIAO MORLIGNE

SGS

scan to see the report

QDHL2104501953SD

Test Report

Report No.: QDHL2104501953SD

Sample Description:	DISPOSABLE NITRILE GLOVES
Applicant:	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.
Test Type:	SUBMITTED BY CLIENT

SGS Building No.10, Zhuzhu Road, Laoshan District, Qingdao, Shandong, China 266061 t (86-532) 68999999 www.sgsgroup.com.cn sgs.china@sgs.com
Member of the SGS Group (SGS SA)

SGS

Report No.: QDHL2104501953SD

Test Report

Sample information	Sample Description	DISPOSABLE NITRILE GLOVES	Color	BLUE
	Received sample quantity	20PCS	Type/ Specifications	XC101
	Lot No.	20210125	Lot Quantity	NOT PROVIDED
	Manufacture Date	20210125	Expiration Date	20230124
	Material/Appearance	NOT PROVIDED	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	/		
Client information	Applicant	GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD.		
	Applicant address	B10, FOURTH FLOOR, NO.137 (PLANT A1), PACIFIC INDUSTRIAL ZONE, XINTANG TOWN, ZENGCHENG DISTRICT, GUANGZHOU.		
Test information	Sample Receiving Date	APR.13,2021	Test Period Date	APR.13,2021 TO APR.23,2021
	Sample No.	QDHL2104501953SD	Test environment	Meet requirement
	Test items	Permeation by liquid chemicals		
	Testing Accordance	EN ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms Clause 5.4		

SGS Building No.10, Zhuzhu Road, Laoshan District, Qingdao, Shandong, China 266061 t (86-532) 68999999 www.sgsgroup.com.cn sgs.china@sgs.com
Member of the SGS Group (SGS SA)

SGS

Report No.: QDHL2104501953SD

Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: APR.23,2021
Remark	/

Approver: Auditor: Compiler: Lillian Diao

Date: APR.23,2021 Date: APR.23,2021 Date: APR.23,2021

SGS Building No.10, Zhuzhu Road, Laoshan District, Qingdao, Shandong, China 266061 t (86-532) 68999999 www.sgsgroup.com.cn sgs.china@sgs.com
Member of the SGS Group (SGS SA)

EN374-3

SGS

Report No.: QDHL2104501953SD

Sample Photo

SGS

Report No.: QDHL2104501953SD

Test Results

Test Items	Test Method	Requirement	Test Result			Assessment
Permeation by liquid chemicals	EN ISO 374-1: 2016+A1:2018 Clause 5.4 EN 16523-1: 2015+A1:2018	/	Chemical CAS No.	Sodium hydroxide 40% 1310-73-2		/
			Thickness of specimens	0.07mm		
				0.07mm		
				0.06mm		
			Visual assessment	No change		
			NST at NPR+1ug/cm²·min⁻¹	>490 min		
				>490 min		
				>490 min		
			Performance level	Level 6	Refer To appendix	
				Level 6		
				Level 6		

Appendix: Permeation by liquid chemical

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Remarks:
1. The test was carried out by external laboratory assessed as competent (Jiangsu Guojian Testing Technology Co., Ltd. CMA No. 161019130764)
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account

End of Report

SGS

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; altered;a copy without the red testing seal of SGS.
2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.
3. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.
4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.
5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address: SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

Tel: 0532-68999187 Zip: 266101 Fax: 0532-80991952

E-mail：Emily.Zhang@sgs.com

EN374-3

广州海关技术中心
GUANGZHOU CUSTOMS DISTRICT TECHNOLOGY CENTER

T4CM8528AU
No: 0105210000671
Date: 21 Jan.2021
Page: 1 of 3

TEST REPORT

APPLICANT: GUAN DONG XINGCANXINGDI Medical Technology CO.,LTD
Room B10,Fourth Floor ,No 133(Plant A1),Pacific Industrial Zone,Xintang Town,Zengcheng District,Guangzhou

SAMPLE DESCRIPTION: The samples submitted by the applicant said to be:

Sample Name:	Disposable medical Nitrile Gloves
Mark:	Lot size :150000 Pcs Size:M
Quantity:	250-Pcs

DATE OF SAMPLE RECEIVED: 15 Jan 2021

TEST PERIOD: 15 Jan 2021-21 Jan 2021

TEST REQUESTED: Test the Dimensions ,Watertightness , Powder-Free Residue according to Standard ASTM D6319-2019 *Standard Specification for Nitrile Examination Gloves for Medical Application*.

TEST RESULT: (Refer to the next page.)

CONCLUSION: According to the test results ,the submitted samples are found to meet the Dimensions ,Watertightness ,Powder-Free Residue requirement of the standard ASTM D6319-2019 *Standard Specification for Nitrile Examination Gloves for Medical Application*.

(To be continued)

AUTHORISED BY

Guo Ren Hong

广州海关技术中心
GUANGZHOU CUSTOMS DISTRICT TECHNOLOGY CENTER

T4CM8528AU
No: 0105210000671
Date: 21 Jan.2021
Page: 2 of 3

TEST REPORT

RESULT DETAILS OF TEST CONDUCTED:

Table 1

Property			Sample Size	Test Result: Data range	Test Result: Nonconformities Number	Acceptance criteria: Requirement	Acceptance criteria: Nonconformities Number	Assessment
Dimensions	Width		13	(91–93)mm	0	Size: M Length:≥ 230mm Width:95±10mm	≤1	Pass
	Length			(240–242) mm	0			
	Thickness	Finger		(0.08–0.09) mm	0	≥0.05mm		
		Palm		(0.05–0.06) mm	0	≥0.05mm		
Watertightness			200	No leakage	0	Observe the water leakage from the gloves after pouring (1000±50)mL water into the gloves	≤10	Pass

Remark:
(1)Test condition (23±2)℃.
(2)The sample size and acceptance are set by the Inspection level and AQL according to standard ISO 2859 given in Table 1 of ASTM D6319-2019.Lot size:150000 Pcs.

Table 2

Property	Test standard	Test Result	Requirement	Assessment
Powder Free Residue	ASTM D6124-2006	1.0mg/glove	≤2.0 mg/glove	Pass

广州海关技术中心
GUANGZHOU CUSTOMS DISTRICT TECHNOLOGY CENTER

T4CM8528AU
No: 0105210000671
Date: 21 Jan.2021
Page: 3 of 3

TEST REPORT

Sample Photo:

* * * * End of Report * * * *

ASTM

Fiscal Year 2021

Certificate of Registration

This certifies that GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD

B10, Fourth Floor, No. 137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District,

Guangzhou, Guangdong, 511300, CHINA

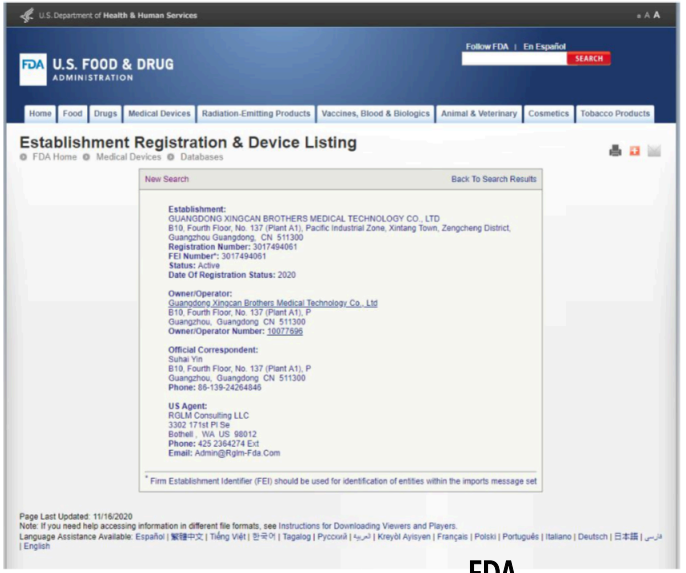
has completed the United States Food and Drug Administration (FDA) medical device registration and listing, pursuant to Part 807, Code of Federal Regulations Title 21 for FY 2021. RGLM consulting has confirmed the registration and listing are currently effective on the date as listed below.

Registration /Owner Operate Number	3017494061
Product Code	LYU
Regulation Number	878.4040
Effective Date of Registration	September 30, 2021
Device Classification Name	ACCESSORY, SURGICAL APPAREL
Device Proprietary Name	Disposable Medical Nitrile gloves,Disposable Medical vinyl gloves,Disposable Medical Mix Nitrile gloves,Disposable Medical latex gloves, Disposable vinyl gloves,Disposable Nitrile Gloves,Disposable mixed nitrile gloves,Disposable latex gloves

This certificate affirms that the above establishment and product(s) are currently registered with U.S. Food and Drug Administration (FDA). This registration and listing will remain effective until the end of Year 2021, unless the establishment terminates the registration and/or product listing. RGLM consulting or this certificate does not make any representations or warranties to denote endorsement or approval of the establishment or its products. RGLM consulting assumes no liability to any person or entity in connection with the foregoing. FDA does not issue or recognize this certificate. RGLM Consulting is not affiliated with the U.S. Food and Drug Administration.

Roy Zhang/ President
RGLM Consulting
admin@rglm-fda.com
United States of America
www.rglm-FDA.com

Seal 2018



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

New Search | Back To Search Results

Establishment:
GUANGDONG XINGCAN BROTHERS MEDICAL TECHNOLOGY CO., LTD
B10, Fourth Floor, No. 137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District,
Guangzhou Guangdong, CN 511300
Registration Number: 3017494061
FEI Number*: 3017494061
Status: Active
Date Of Registration Status: 2020

Owner/Operator:
Guangdong Xingcan Brothers Medical Technology Co., Ltd
B10, Fourth Floor, No. 137 (Plant A1), P
Guangzhou, Guangdong CN 511300
Owner/Operator Number: 10077996

Official Correspondent:
Suhai Yin
B10, Fourth Floor, No. 137 (Plant A1), P
Guangzhou, Guangdong CN 511300
Phone: 86-139-24264846

US Agent:
RGLM Consulting LLC
3302 171st Pl Se
Bothell, WA US 98012
Phone: 425 2364274 Ext
Email: Admin@Rglm-Fda Com

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 11/16/2020
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/09022021.7

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Guangdong Xingcan Brothers Medical Technology Co., Ltd.
B10, Fourth Floor, No.137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District, Guangzhou

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/269/2021**

CE

Issued on: 09/02/2021

Valid until: 08/02/2022

Authorized Signatory
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com

EC REP CERTIFICATE

ANNEX I Medical Device Products

Medical Nitrile Examination Gloves

Medical Vinyl Examination Gloves

Medical Latex Examination Gloves

Medical Vinyl/Nitrile blended Gloves

CE

www.cmcmedicaldevices.com

CE - MECIAL DEVICES

AGREEMENT EC REP
CMC MEDICAL DEVICES 200301

This Agreement made on February 02, 2021 between **Guangdong Xingcan Brothers Medical Technology Co., Ltd.** Located in **B10, Fourth Floor, No.137 (Plant A1), Pacific Industrial Zone, Xintang Town, Zengcheng District, Guangzhou.** (hereinafter referred to as "COMPANY") and **M/s CMC Medical Devices & Drugs S.L.** located in C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain (hereinafter referred to as "Authorized Representative")

Have agreed as follows with regard to the handling of all products (hereinafter called "Products") manufactured by Company and sold to EU in order to comply to the requirements set out in the COUNCIL DIRECTIVE 93/42/EEC Concerning Medical Devices (MDD), Regulation (EU) 2017/745 or 98/79/EC, Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices (as per applicability) and latest version of "Guidelines on a Medical Devices Vigilance System".

Appointment
Company hereby appoints Authorized Representative, who accepts such appointment, as a representative for the "Business Area" and "Product Categories" set out in Appendix A. The responsibility of both parties is as stated hereafter. Service of European Authorized Representative cover the MDD 93/42/EEC or 98/79/EEC. The service will cover the new Regulation (EU) 2017/745 and (EU)2017/746 on medical devices and in vitro diagnostic when this regulation take effect.

Claim Handling
Authorized Representative shall notify company about any received claims and any change of laws and regulations related to company's products set out in Appendix A. Company is the immediate responsible person for the claim handling and regulation compliance.

Accident Handling
On receiving information of an incident (accident), as defined in the MDD 93/42/EEC, Regulation (EU) 2017/745 or 98/79/EC, Regulation (EU) 2017/746 (as per applicability) and MEDDEV 2.12-1 "Guidelines on a Medical Devices Vigilance System", the following procedures shall be applied:

Authorized Representative shall notify occurrence of an incident in its business area to Company immediately upon receiving of incident.
Upon receiving information of any incident Company shall perform the necessary analysis of the situation immediately and send the incident report to Authorized Representative according to the requirements of latest version of "Guidelines on a Medical Devices Vigilance System". In that way Authorized Representative can submit the report

to the relevant Competent Authority as defined in the timescale of latest version of "Guidelines on a Medical Devices Vigilance System".

If applicable, based on the report Company shall instruct Authorized Representative of the necessary countermeasures to be taken. Authorized Representative shall inform the relevant Competent Authority and customer as required in the countermeasure plan issued by Company.

Responsibilities on Technical Documentation:

i. Company shall establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity for the "Product Categories" set out in Appendix A to be able to comply with the MDD and MDR requirements.
ii. Company shall transfer the agreed Technical Documentation and Declaration of Conformity to Authorized Representative upon request.
iii. Company shall have the responsibility to provide to Authorized Representative any additional documentation as required by the Competent Authority or Notified Body.
iv. The authorized representative shall provide a copy of this agreement to the competent authority, upon request.

Instruction Manual (If applicable)
Company shall be responsible for the content of instruction (user's) manuals, and shall ensure that English language instruction manuals are available to Authorized Representative. Company shall ensure that the required local language instruction manuals are provided to the customers.

Registration

The Authorized Representative shall register or notify the products set out in Appendix A to the Competent Authority of the member state in which he has his registered place of business.

Company shall have all data allowing for identification of concerned devices together with the label and the instruction for use available to authorized representative upon request by competent authority.

Tasks to be performed by Authorized Representative:
i. Verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the company;
ii. Keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and

supplements, available for the competent authorities for a period of at least 10 years after the last device covered by the eu declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market;
iii. Comply with the registration obligations laid down in article 31 of MDR/2017/745 OR art 28 of MDR /2017/746 and verify that the company has complied with the registration obligations laid down in articles 27 and 29 MDR/2017/745 OR art 24 and 26 of MDR/2017/746;
iv. In response to a request from a competent authority, provide that the competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official union language determined by the member state concerned.
v. Forward to the company any request by a competent authority of the member state in which the authorized representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;
vi. Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
vii. Terminate this agreement if the company acts contrary to its obligations under this regulation;
viii. Authorized representatives will have permanently and continuously at their disposal at least one person responsible for regulatory compliance (PRRC) who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.

Obligations of Manufacturer Company:

i. COMPANY must comply with all the requirements specified in Article 10 MDR - Regulation 2017/745 or art 10 MDR 746/2017 regarding general obligations of manufacturers.
ii. COMPANY shall procure and maintain at all times during the term of this Agreement a Product liability insurance covering the products placed on the European market. This liability insurance should include "EAR" as well. This insurance, however, will not protect "EAR" against liability which results from its unauthorized Activities, wrongful or negligent acts of omission, or breach of this Agreement.
This agreement will not be valid if the manufacturer does not meet this requirement.

Other Obligations of Authorized Representative & Company:

i. The authorized representative shall provide all documentation and information that a market surveillance authority may require for the purpose of market surveillance.
ii. The authorized representatives shall rescind his contract with the company if the latter does not provide him with the access to the necessary information.
iii. Company shall keep authorized representative informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning paragraphs a) to c) hereunder shall be informed.

a) Safeguard Clause

i. "Where a Member State ascertains that any of the medical devices specified in Appendix A, when correctly used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service." If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such measures to the company and advise the company as to the implications of this decision.
ii. When the Commission finds that national measures taken under the Safeguard Clause "are unjustified, it shall immediately so inform the Member State which took the measures and the company or authorized representative". If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.

b) Vigilance

i. In case of an incident and If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.
ii. The company should ensure that the involved authorized representative is kept informed of incident reports and Field Safety Corrective Actions.

c) Serious adverse events during clinical investigation, i.e. in the premarket phase

i. According to Article 80 of MDR 745/2017 and art 76 of 746/2017, "all serious adverse events must be fully recorded and immediately notified to all Competent Authorities of the Member States in which the clinical investigation is being performed by the sponsor".
ii. Authorized representative should inform the company of decisions of a Member State in respect of refusal or restriction of the placing the devices specified in Appendix A in the market.

(Appendix A): (product list)

Medical Nitrile Examination Gloves
Medical Vinyl Examination Gloves
Medical Latex Examination Gloves
Medical Vinyl/Nitrile blended Gloves

The following countries represent Authorized Representative's Business Area:

EUROPEAN COMMUNITY TERRITORY

Annual Fee:

Validity of Agreement : This agreement shall stand valid up to **February 01, 2022**. The Company shall apply for renewal of the agreement at least 30 days prior to expiry of this agreement.

Guangdong Xinyicai Brothers Medical Technology Co., Ltd. (COMPANY)

Authorized Signatory

Country on February 02, 2021.

CMC MEDICAL DEVICES & DRUGS S.L.
(EC REP AUTHORIZED REPRESENTATIVE)

Authorized Signatory

Spain on February 02, 2021.

2020 ACHIEVEMENT

✪ In 2020, WE are proud to mobilize our resources to help the governments of Morocco, Gabon, Mali, Burkina Faso and Côte d'Ivoire to meet the needs of hospitals in terms of the cold chain, masks and gloves.

INTERNATIONAL FOOTPRINT

Office in:
Hong Kong - Guangzhou - Yiwu - Moscow - Casablanca - Paris - New York.

We **think global** and **act locally** in the main international markets

THEY TRUST US

OJCOMPANY
PHARMAFORALL
NanoPV
LIDL
COSCO SHIPPING
iReplace expertise
STAP
ABGC
NATIONAL GEOGRAPHIC
Editions Gallimard


MORLIGNE
XCYILIAO
THANK YOU
www.morlignegroup.com
www.xcyiliao.com