■ PRODUCT DESCRIPTION

Product Model	GVN	GV	GVC
Type	Nitrile ☑	Synthetic protective ☑	Vinyl ☑
Material	Nitrile (Latex-Free)	Nitrile / Vinyl (Latex-Free)	Vinyl (Latex-Free)
Standard	EN455 / EN420+EN374-5 / ASTM D6319 / GB10213	EN455 / EN420+EN374-5 / ASTM D5250 / GB24786 / GB4806.7	
Colour	Blue■☑ Pink■☐ Purple■☑ White■☑		
All Size:	Small(S) / Medium(M) / Large (L) / Extra Large(XL)		
Powder	Powder-Free		
Usage	Medical Use / General Protection		
Availability	Intended to be used on one individual during a single procedure		
Country of Origin	CHINA		
Manufacturer	xxxxxxxxxxxxxxxxxxxx		

■ Weight & Size

Pour vous assurer que vos gants ont le meilleur ajustement et la meilleure sensation, nous avons créé ce tableau de tailles pratique. Veuillez garder à l' esprit que les gants sont comme des chaussures: il existe des tailles générales, mais différents styles s' adapteront différemment. Veuillez trouver la taille de votre gant mesurant votre main en utilisant le guide ci-dessous.

Small(**S**)	Hand width 80-90 mm , 3.5±0.5g
Medium(**M**)	Hand width 90-100mm , 4.0±0.5g
Large (**L**)	Hand width 100-110 mm , 4.5±0.5g
X Large (**XL**)	Hand width 110-120 mm , 5.0±0.5g

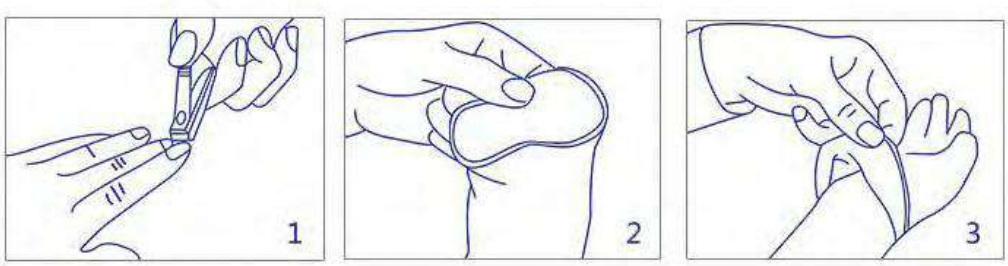
■ Color

Blue	Pink	Purple	White
			

■ Description des graphiques et des symbols

1	CE	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.
2		Indicates the medical device manufacturer, as defined in EU Directives 93/42/EEC and EU PPE 2016/425.
3	EC REP	Indicates the Authorized representative in the European Community.
4		DATE OF MANUFACTURE. This symbol shall be accompanied by a date to indicate the date of manufacture
5		Do not re-use
6		Use-by date
7	LOT	Lot number

■ INSTRUCTION



Veuillez couper vos ongles avant de porter les gants, car vos ongles peuvent casser les gants s' ils sont trop longs ou trop tranchants. Pulpe des doigts le long de l' intérieur des gants, puis mettez votre main dans les gants; (3) Lorsque vous enleverez les gants, veuillez enrouler le brassard, face aux doigts.

■ Executive Standard

产品序列 Product sequence	注册或认证区域 Registration or certification area	执行标准 Executive Standard
医用丁腈检查手套 Nitrile Examination Gloves	中国 NMPA	GB10213
	欧盟 CE	EN455
	美国 FDA、510k Exempt	ASTM D6319
医用 PVC 检查手套 Vinyl Examination Gloves	中国 NMPA	GB24786
	欧盟 CE	EN455
	美国 FDA、510k Exempt	ASTM D5250
一次性使用丁腈手套 Disposable Nitrile Gloves	中国食品级	GB4806.11
	欧盟 CE PPE	EN ISO 21420 EN ISO 374
	美国 FDA、510k Exempt	ASTM D7866
一次性使用 PVC 手套 Disposable Vinyl Gloves	中国食品级	GB4806.7
	欧盟 CE PPE	EN ISO 21420 EN ISO 374
	美国 FDA、510k Exempt	ASTM D7866
合成防护手套 Synthetic Protective Gloves	中国食品级	GB4806.7
	欧盟 CE PPE	EN ISO 21420 EN ISO 374
	美国 FDA、510k Exempt	ASTM D7866

Certificate & Test report

- CHINA Certificate For Exportation Of Medical Products
- Business License
- Export enterprise registeration form
- Customs filing form
- GS1 China Membership License
- NMPA Medical Examination Gloves registration certificate
- NMPA Medical Examination Gloves production license
- FDA 510(K) Exempt
- ISO13485 certificate
- Declaration of Conformity
- Certificate of registration with the EU authorities
- Doc of authorized representatives of the EU Union
- SGS Test Report—Nitrile Examination Gloves (EN455)
- SGS Test Report—Nitrile Examination Gloves (ASTM D6319)
- CTC Test Report—Disposable Nitrile Gloves (EN420+EN374-5)
- CTT Test Report—Disposable Nitrile Gloves (GB4806.11)
- SGS Test Report—Vinyl Examination Gloves (EN455)
- CTC Test Report—Disposable Vinyl Gloves (EN420+EN374-5)
- CTT Test Report—Disposable Vinyl Gloves (GB4806.7)
- CTC Test Report—Synthetic Protective Gloves (EN420+EN374-5)
- GTTC Test Report—Synthetic Protective Gloves (GB4806.7)

Certificat CHINE pour l'exportation de produits médicaux

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号:
Certificate NO.:

产品名称: 医用检查手套
Product(s): Medical Examination Gloves

规格型号: 按材质分: 丁腈无粉手套(GN)、PVC 无粉手套(GVC); 按尺寸分: 特小号(XS)、小号(S)、中号(M)、大号(L)、特大号(XL)
Model: According to the material points: Nitrile powder free gloves (GN) and PVC powder free gloves (GVC); According to size points: XS、S、M、L、XL;

产品注册或备案凭证号:
Registration certificate(s): Registered NO. of Sichuan Chengdu Medical products Administration

生产企业:
Manufacturer:

生产企业住所:
区 9 号
Address of manufacturer:

生产许可或备案凭证号:
Manufacturing License(s): Production Registered NO. of Sichuan Chengdu Medical products Administration

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至: 2022 年 11 月 12 日
This certification valid until:

备注:
Remark:

四川省药品监督管理局 行政审批专用章

2020 年 11 月 13 日
(出具单位盖章)

第 1 页 共 1 页

Business License

统一社会信用代码
9151011[redacted]

营业执照

(副本)

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名　　称 [redacted]

类　　型 有限责任公司(自然人投资或控股)

法定代表人 [redacted]

经营范围 医疗器械、电子产品的设计、研发、生产、销售及技术咨询、技术转让、技术服务；生产、销售：口罩、劳保用品、针纺织品、塑料制品、橡胶制品、消毒用品（不含危险化学品）、机械设备、自动化设备；专业设计服务；企业管理咨询服务；货物及技术进出口。（依法须经批准的项目，经相关部门批准后方可展开经营活动）。

注册资本 贰仟陆佰壹拾肆万叁仟柒佰玖拾元整

成立日期 2018年10月31日

营业期限 2018年10月31日 至 长期

住　　所 [redacted]

登记机关 [redacted]市[redacted]区市场监督管理局

2020 年 8 月 5 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

- **Formulaire d'enregistrement des entreprises d'exportation**

对外贸易经营者备案登记表

备案登记表编号：　　统一社会信用代码：
进出口企业代码：

经营者中文名称			
经营者英文名称			
组织机构代码		经营者类型（由备案登记机关填写）	有限责任公司
住　所			
经营场所（中文）			
经营场所（英文）			
联系电话		联系传真	
邮政编码		电子邮箱	
工商登记注册日期	2018-10-31	工商登记注册号	

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名		有效证件号	
注册资金	贰仟陆佰壹拾肆点叁柒玖万元	（折美元）	

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产		（折美元）	

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关
签章
2020 年　08 月　27 日

Customs filing form

海关进出口货物收发货人备案回执

企业名称	[redacted]
统一社会信用代码	[redacted]
海关备案日期	2019-10-10
海关编码	[redacted]
检验检疫备案号	[redacted]
有效期	长期

锦城海关
2019年10月11日

自然人、法人或者非法人组织可通过“中国海关企业进出口信用信息公示平台”（http://credit.customs.gov.cn）或者“互联网+海关”（http://online.customs.gov.cn）查询海关公示的企业信息。

- **Licence d' adhésion GS1 Chine**

中国商品条码系统成员证书
GS1 China Membership License

物编注字第 [redacted] 号
Certificate No

成员名称：
Prefix Licensee's Name [redacted]

注册地址：
Registration Address [redacted]

QR码 汉信码

厂商识别代码：
GS1 Company Prefix（GCP） [redacted]

厂商识别代码可用于生成下述标识代码：
GS1 Company Prefix is used to create the following GS1 Identification Keys:

全球贸易项目代码（GTIN） 全球位置码（GLN） 系列货运包装箱代码（SSCC） 全球型号代码（GMN）
全球可回收资产代码（GRAI） 全球单个资产代码（GIAI） 全球服务关系代码（GSRN） 全球文件类型代码（GDTI）
全球货物托运标识代码（GINC） 全球货物装运标识代码（GSIN）
持有本证书的成员对厂商识别代码及上述标识代码享有专用权。
The GS1 Company Prefix and other ID keys shown above are licensed for the sole use of the member named on this certificate.

机构全球位置码：
Legal Entity Global Location Number (GLN) [redacted]

有效期：2020年08月06日 至 2022年08月06日
This License shall become effective as of 06/08/2020 (d/m/y) and remain valid until 06/08/2022 (d/m/y).

NO. [redacted]

GS1 China 中國物品編碼中心

中国物品编码中心

- **Certificat d'enregistrement des gants d'examen médical NMPA**

第一类医疗器械备案信息表

备案号：[redacted]

备案人名称	[redacted]
备案人组织机构代码	[redacted]
备案人注册地址	[redacted]
生产地址	[redacted]
代理人	/
代理人注册地址	/
产品名称	医用检查手套
型号/规格	按材质分：丁腈无粉手套（GN）、PVC 无粉手套（GVC）；按尺寸分：特小号（XS）、小号（S）、中号（M）、大号（L）、特大号（XL）
产品描述	通常采用聚氯乙烯、橡胶等材料制造。有足够的强度和阻隔性能。非无菌提供，一次性使用。
预期用途	用于戴在医生手上或手指上对患者病情进行检查或触检。
备注	
备案单位和日期	成都市市场监督管理局 备案日期：2020 年 09 月 28 日
变更情况	

第一类医疗器械备案凭证

[redacted]

根据相关法规要求，对你单位第一类医疗器械：医用检查手套，予以备案，备案号：[redacted]，

成都市市场监督管理局

（盖章）

日期：2020 年 09 月 28 日

- **Licence de production de gants d'examen médical NMPA**

第一类医疗器械生产备案凭证

备案编号：[redacted]

企业名称	[redacted]		
住　所	[redacted]		
生产地址	[redacted]		
法定代表人	[redacted]	企业负责人	[redacted]
生产范围	2002分类目录 I类:6866-3-病人防护用品 2017分类目录 I类:14-14-医护人员防护用品		

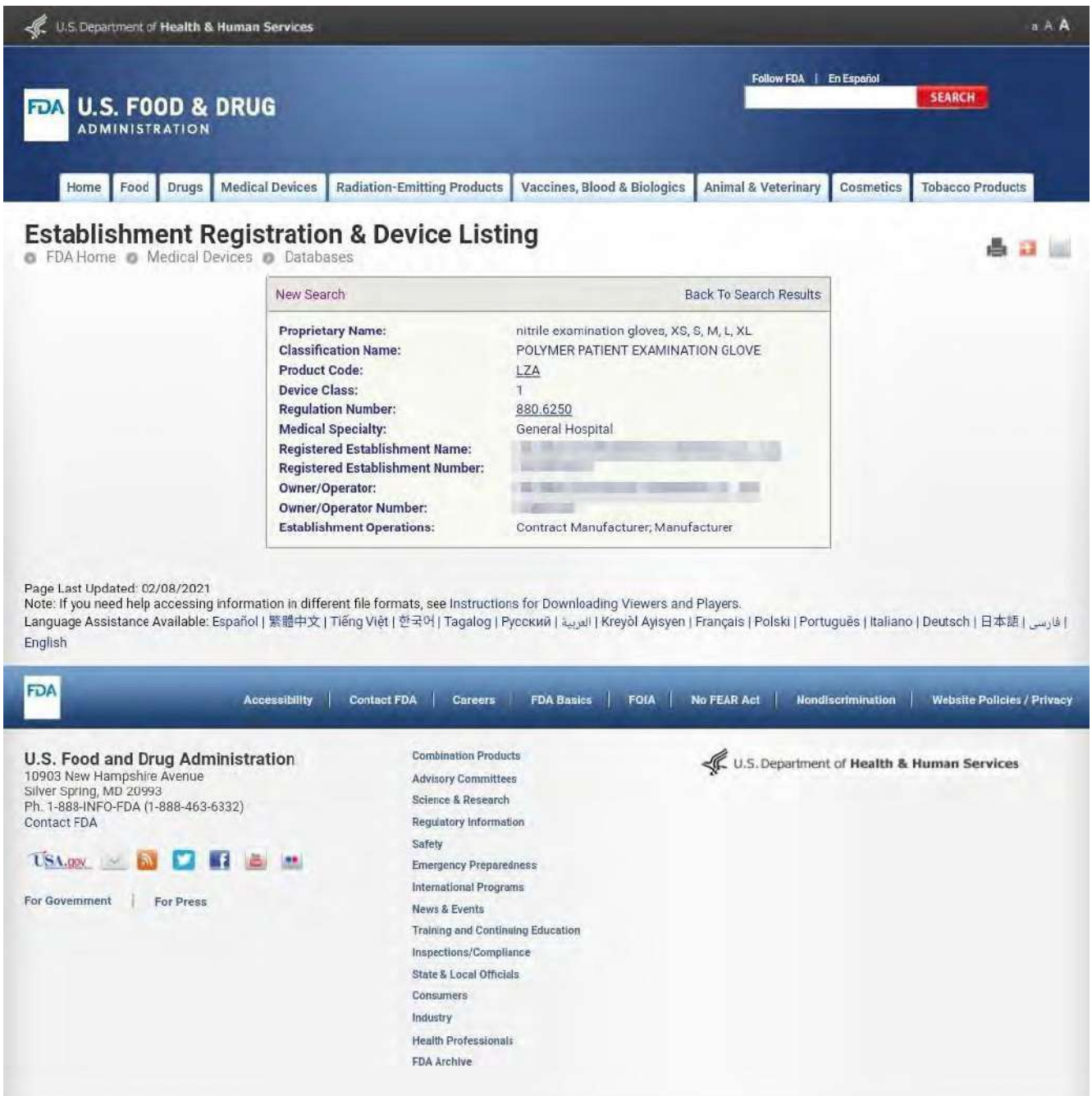
生产产品列表	产品名称	产品备案号	登载日期	备注
	医用检查手套	[redacted]	2020-10-20	

备案部门（公章）：四川省成都市市场监督管理局

备案日期：2020年10月20日

成都市市场监督管理局 行政审批备案专用章 (2)

- **FDA 510K Exempt / Gants d' examen en nitrile**



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

Proprietary Name:	nitrile examination gloves, XS, S, M, L, XL
Classification Name:	POLYMER PATIENT EXAMINATION GLOVE
Product Code:	LZA
Device Class:	1
Regulation Number:	880.6250
Medical Specialty:	General Hospital
Registered Establishment Name:	[redacted]
Registered Establishment Number:	[redacted]
Owner/Operator:	[redacted]
Owner/Operator Number:	[redacted]
Establishment Operations:	Contract Manufacturer; Manufacturer

Page Last Updated: 02/08/2021
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 | Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies / Privacy

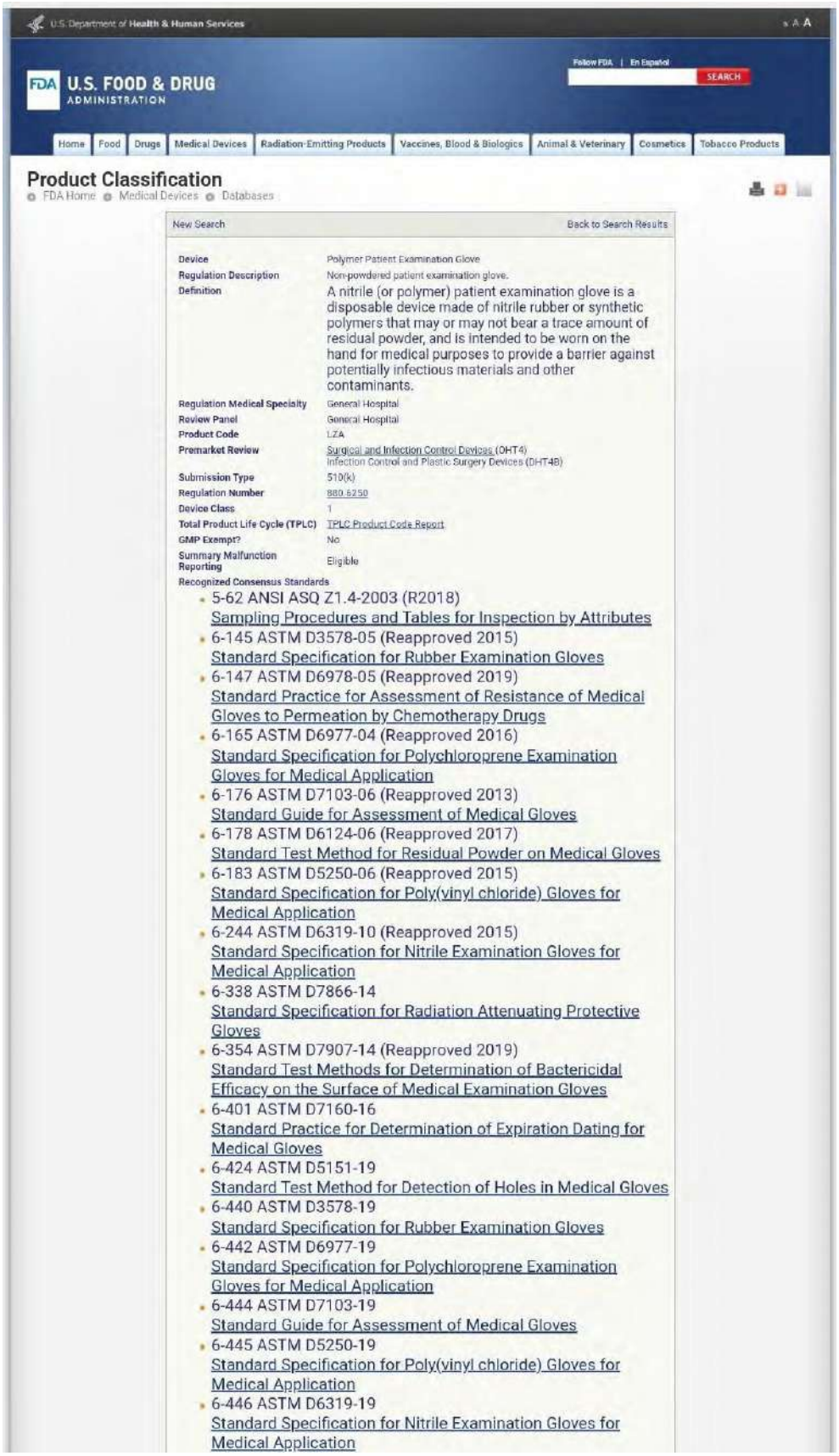
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government | For Press

Combination Products
Advisory Committees
Science & Research
Regulatory Information
Safety
Emergency Preparedness
International Programs
News & Events
Training and Continuing Education
Inspections/Compliance
State & Local Officials
Consumers
Industry
Health Professionals
FDA Archive

U.S. Department of Health & Human Services



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

Product Classification

FDA Home > Medical Devices > Databases

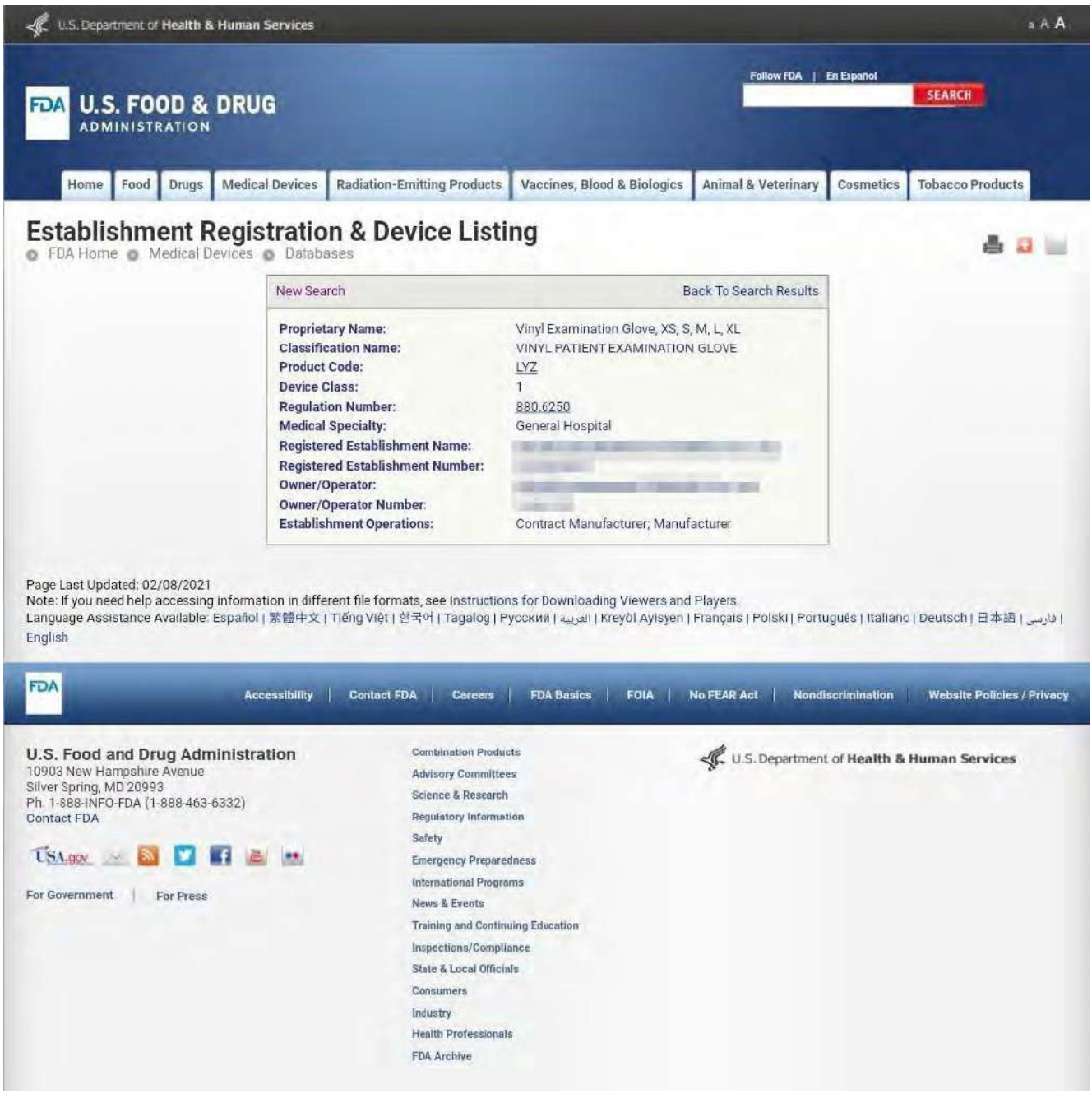
New Search | Back to Search Results

Device	Polymer Patient Examination Glove
Regulation Description	Non-powdered patient examination glove.
Definition	A nitrile (or polymer) patient examination glove is a disposable device made of nitrile rubber or synthetic polymers that may or may not bear a trace amount of residual powder, and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	LZA
Premarket Review	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(k)
Regulation Number	880.6250
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Recognized Consensus Standards

- 5-62 ANSI ASQ Z1.4-2003 (R2018)
  Sampling Procedures and Tables for Inspection by Attributes
- 6-145 ASTM D3578-05 (Reapproved 2015)
  Standard Specification for Rubber Examination Gloves
- 6-147 ASTM D6978-05 (Reapproved 2019)
  Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- 6-165 ASTM D6977-04 (Reapproved 2016)
  Standard Specification for Polychloroprene Examination Gloves for Medical Application
- 6-176 ASTM D7103-06 (Reapproved 2013)
  Standard Guide for Assessment of Medical Gloves
- 6-178 ASTM D6124-06 (Reapproved 2017)
  Standard Test Method for Residual Powder on Medical Gloves
- 6-183 ASTM D5250-06 (Reapproved 2015)
  Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
- 6-244 ASTM D6319-10 (Reapproved 2015)
  Standard Specification for Nitrile Examination Gloves for Medical Application
- 6-338 ASTM D7866-14
  Standard Specification for Radiation Attenuating Protective Gloves
- 6-354 ASTM D7907-14 (Reapproved 2019)
  Standard Test Methods for Determination of Bactericidal Efficacy on the Surface of Medical Examination Gloves
- 6-401 ASTM D7160-16
  Standard Practice for Determination of Expiration Dating for Medical Gloves
- 6-424 ASTM D5151-19
  Standard Test Method for Detection of Holes in Medical Gloves
- 6-440 ASTM D3578-19
  Standard Specification for Rubber Examination Gloves
- 6-442 ASTM D6977-19
  Standard Specification for Polychloroprene Examination Gloves for Medical Application
- 6-444 ASTM D7103-19
  Standard Guide for Assessment of Medical Gloves
- 6-445 ASTM D5250-19
  Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
- 6-446 ASTM D6319-19
  Standard Specification for Nitrile Examination Gloves for Medical Application

- **FDA 510K Exempt / Gants d' examen en vinyle**



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

Proprietary Name:	Vinyl Examination Glove, XS, S, M, L, XL
Classification Name:	VINYL PATIENT EXAMINATION GLOVE
Product Code:	LYZ
Device Class:	1
Regulation Number:	880.6250
Medical Specialty:	General Hospital
Registered Establishment Name:	
Registered Establishment Number:	
Owner/Operator:	
Owner/Operator Number:	
Establishment Operations:	Contract Manufacturer; Manufacturer

Page Last Updated: 02/08/2021
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 | Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies / Privacy

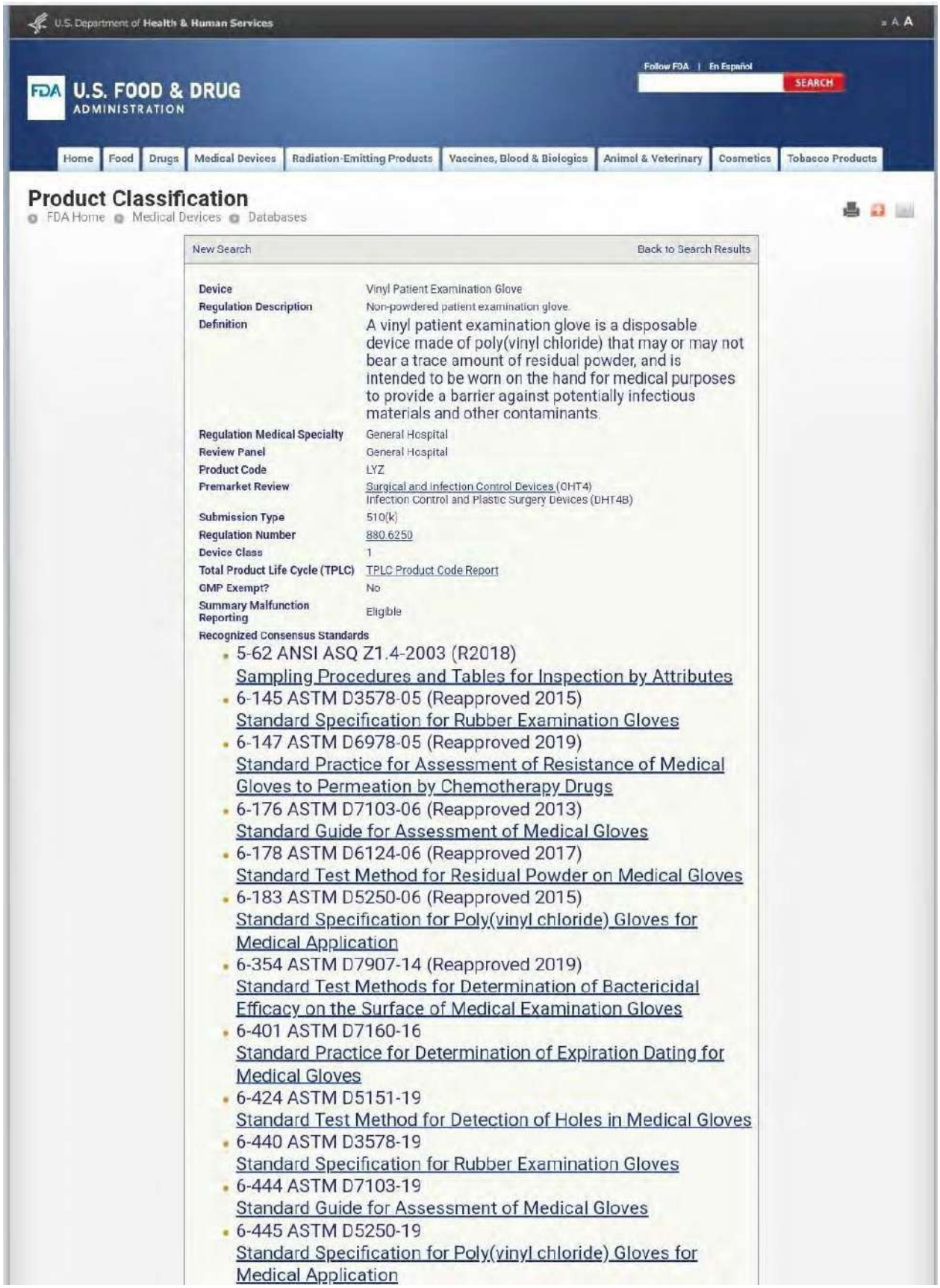
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government | For Press

Combination Products
Advisory Committees
Science & Research
Regulatory Information
Safety
Emergency Preparedness
International Programs
News & Events
Training and Continuing Education
Inspections/Compliance
State & Local Officials
Consumers
Industry
Health Professionals
FDA Archive

U.S. Department of Health & Human Services



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

Product Classification

FDA Home > Medical Devices > Databases

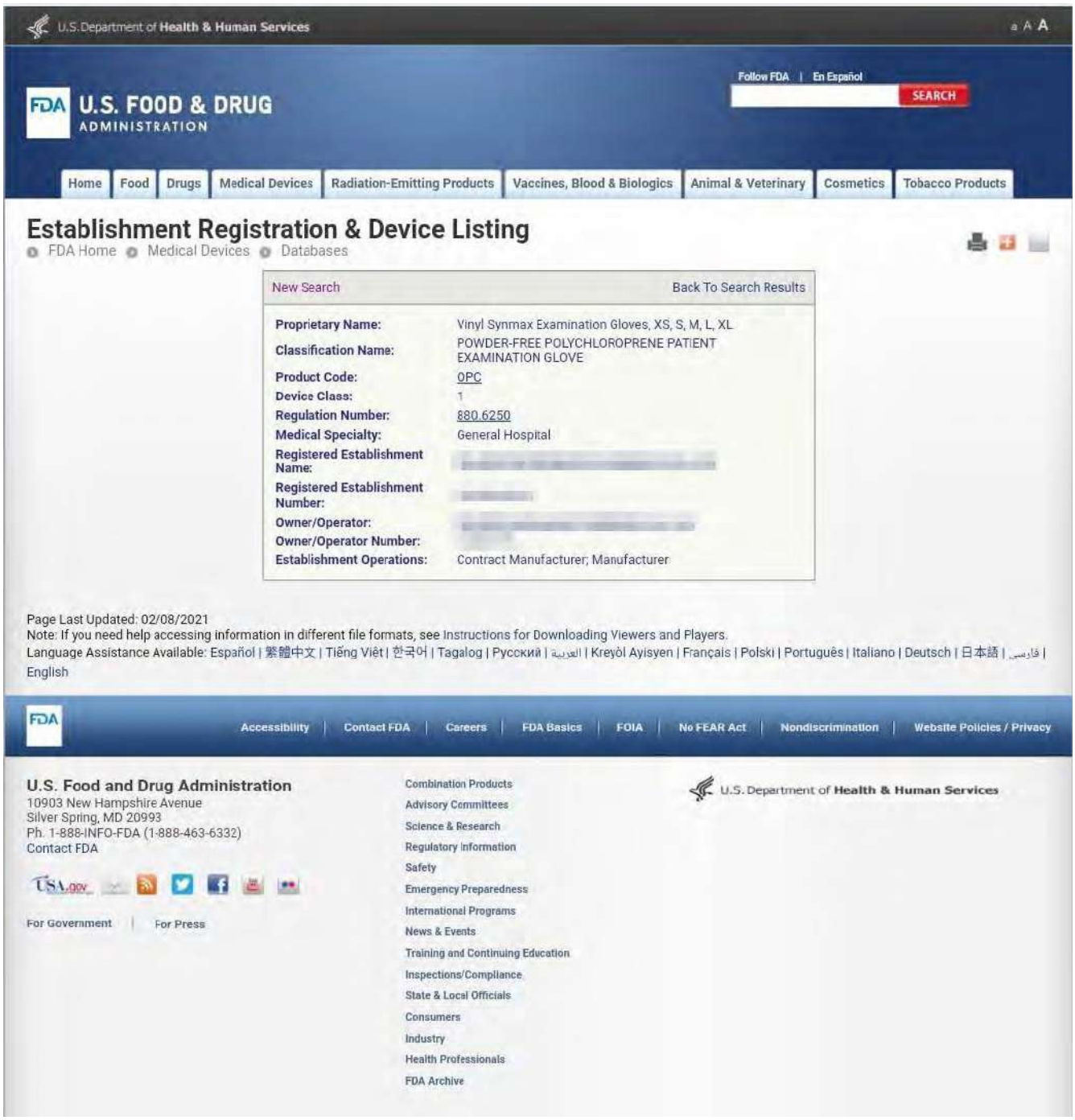
New Search | Back to Search Results

Device	Vinyl Patient Examination Glove
Regulation Description	Non-powdered patient examination glove.
Definition	A vinyl patient examination glove is a disposable device made of poly(vinyl chloride) that may or may not bear a trace amount of residual powder, and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	LYZ
Premarket Review	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(k)
Regulation Number	880.6250
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Recognized Consensus Standards

- 5-62 ANSI ASQ Z1.4-2003 (R2018)
  Sampling Procedures and Tables for Inspection by Attributes
- 6-145 ASTM D3578-05 (Reapproved 2015)
  Standard Specification for Rubber Examination Gloves
- 6-147 ASTM D6978-05 (Reapproved 2019)
  Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- 6-176 ASTM D7103-06 (Reapproved 2013)
  Standard Guide for Assessment of Medical Gloves
- 6-178 ASTM D6124-06 (Reapproved 2017)
  Standard Test Method for Residual Powder on Medical Gloves
- 6-183 ASTM D5250-06 (Reapproved 2015)
  Standard Specification for Poly(vinyl chloride) Gloves for Medical Application
- 6-354 ASTM D7907-14 (Reapproved 2019)
  Standard Test Methods for Determination of Bactericidal Efficacy on the Surface of Medical Examination Gloves
- 6-401 ASTM D7160-16
  Standard Practice for Determination of Expiration Dating for Medical Gloves
- 6-424 ASTM D5151-19
  Standard Test Method for Detection of Holes in Medical Gloves
- 6-440 ASTM D3578-19
  Standard Specification for Rubber Examination Gloves
- 6-444 ASTM D7103-19
  Standard Guide for Assessment of Medical Gloves
- 6-445 ASTM D5250-19
  Standard Specification for Poly(vinyl chloride) Gloves for Medical Application

FDA 510K Exempt / Gants d' examen Symax en vinyle



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

Proprietary Name:	Vinyl Synmax Examination Gloves, XS, S, M, L, XL
Classification Name:	POWDER-FREE POLYCHLOROPRENE PATIENT EXAMINATION GLOVE
Product Code:	OPC
Device Class:	1
Regulation Number:	880.6250
Medical Specialty:	General Hospital
Registered Establishment Name:	[redacted]
Registered Establishment Number:	[redacted]
Owner/Operator:	[redacted]
Owner/Operator Number:	
Establishment Operations:	Contract Manufacturer; Manufacturer

Page Last Updated: 02/08/2021
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 | Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies / Privacy

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government | For Press

Combination Products
Advisory Committees
Science & Research
Regulatory Information
Safety
Emergency Preparedness
International Programs
News & Events
Training and Continuing Education
Inspections/Compliance
State & Local Officials
Consumers
Industry
Health Professionals
FDA Archive

U.S. Department of Health & Human Services

Product Classification

FDA Home › Medical Devices › Databases

New Search | Back to Search Results

Device	Powder-Free Polychloroprene Patient Examination Glove
Regulation Description	Non-powdered patient examination glove.
Definition	A powder free polychloroprene patient examination glove is a disposable device made of polychloroprene rubber tthat bears powder to facilitate donning, and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.
Physical State	A powder free polychloroprene patient examination glove is a disposable device made of polychloroprene rubber tthat bears powder to facilitate donning, and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.
Technical Method	A powder free polychloroprene patient examination glove is a disposable device made of polychloroprene rubber tthat bears powder to facilitate donning, and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.
Target Area	glove
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	OPC
Premarket Review	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(k)
Regulation Number	880.6250
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No

Third Party Review

- Eligible for *Accredited Persons Program*

Accredited Persons

- Accelerated Device Approval Services
- Center For Measurement Standards Of Industrial
- Global Quality And Regulatory Services
- Regulatory Technology Services, Llc
- Sgs North America
- Third Party Review Group, Llc

- **FDA 510K Exempt / Gants de protection**

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

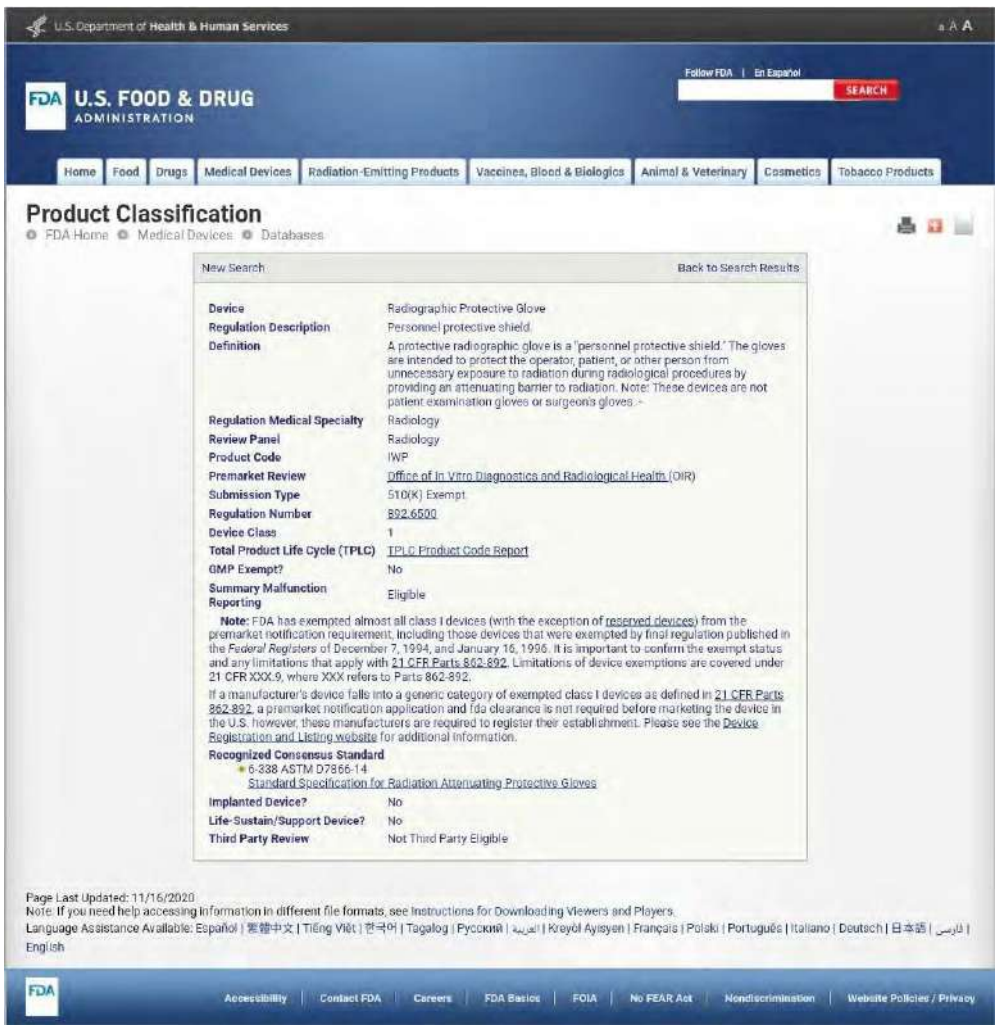
FDA Home | Medical Devices | Databases

New Search | Back To Search Results

Proprietary Name:	Protective Glove
Classification Name:	RADIOGRAPHIC PROTECTIVE GLOVE
Product Code:	IWP
Device Class:	1
Regulation Number:	892.6500
Medical Specialty:	Radiology
Registered Establishment Name:	[redacted]
Registered Establishment Number:	[redacted]
Owner/Operator:	[redacted]
Owner/Operator Number:	[redacted]
Establishment Operations:	Contract Manufacturer, Manufacturer

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 Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies / Privacy



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

Product Classification

FDA Home | Medical Devices | Databases

New Search | Back to Search Results

Device	Radiographic Protective Glove
Regulation Description	Personnel protective shield.
Definition	A protective radiographic glove is a "personnel protective shield." The gloves are intended to protect the operator, patient, or other person from unnecessary exposure to radiation during radiological procedures by providing an attenuating barrier to radiation. Note: These devices are not patient examination gloves or surgeon's gloves. -
Regulation Medical Specialty	Radiology
Review Panel	Radiology
Product Code	IWP
Premarket Review	Office of In Vitro Diagnostics and Radiological Health (OIR)
Submission Type	510(K) Exempt
Regulation Number	892.6500
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

Recognized Consensus Standard
- 6-338 ASTM D7866-14
  Standard Specification for Radiation Attenuating Protective Gloves

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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 Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies / Privacy

ISO13485 Certificate

UKAS

MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATE

No: [redacted]-Z

Awarded to

[redacted]

Building9,Section1,No.618 of West Kelin Road,Chengdu Cross-Straits Technology Industry Development Zone,Wenjiang District,Chengdu

The established quality management system has been reviewed and approved.

YY/T 0287-2017 idt ISO 13485:2016

Certification range:

R&D,Production and Sales of Medical Face Mask,Surgical Mask,Disposable Mask,Particle Filtering Half Mask,KN95 Mask,Filtering Half Mask,FFP2 Mask,Respiratory Protection Products,Medical Nitrile Examination Gloves,Medical Vinyl Examination Gloves,Disposable Gloves, Disposable Protective Gloves,Medical Isolation Gown,Medical Protective Shoes,Anti-fog Medical Goggles,Isolation Mask,Labor Protection Products,Needle Textiles,Medical Nebulizers Houttuyniacordata Extract, Medical Cold Compresses.

Under the condition that the certificate holder's management system continues to meet the medical device quality management system standards, the certification is valid for three years. And check it online at www.ukas-china.com. The validity of this certificate shall be confirmed by the Center through regular supervision and approval.

Certificate registration date: 28 April,2020 **Certificate is valid until:** 27 April,2023

UKAS QUALITY MANAGEMENT

IAF

Signed by:

UKAS SAIBAO SYSTEM CERTIFICATION (CHINA) CO.,LTD.

UKAS赛宝体系认证（中国）有限公司

www.ukas-china.com

Déclaration de conformité / CE

Declaration of Conformity

Manufacturer:	[redacted]
European Representative:	[redacted]
Product Name	**Disposable Gloves**
Model Number:	5R-GV （S、M、L）
	5R-GVN （S、M、L）
	5R-GVC （S、M、L）
UMDNS-Code:	11879
Registration Number:	RPS/1601/2020
Executive Standard:	EN455

Classification (MDD, Annex IX): Class I Rule 1

Conformity Assessment Route: **Annex VII**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Manufacturer takes full responsibility of the content of Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC modified with the Directive 2007/47

Signature:

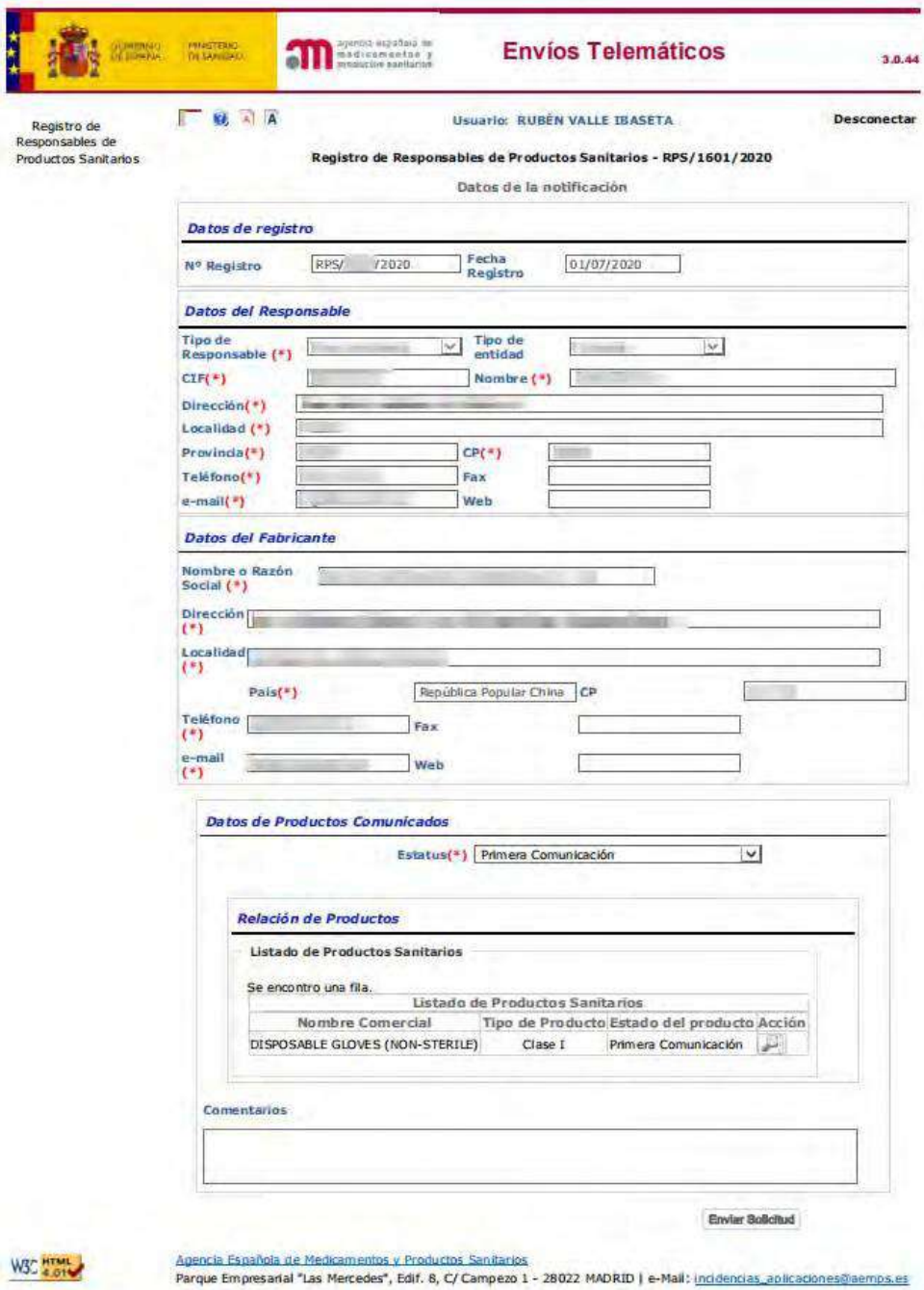
Name: Pan Yuzhang

Place& Date: Chengdu 2020-06-28

Position: Management Representative

CE

- **Certificat d'enregistrement auprès des autorités de l'UE**



Envíos Telemáticos 3.0.44

Registro de Responsables de Productos Sanitarios

Usuario: RUBÉN VALLE IBASETA Desconectar

Registro de Responsables de Productos Sanitarios - RPS/1601/2020

Datos de la notificación

Datos de registro

Nº Registro RPS/ /2020 Fecha Registro 01/07/2020

Datos del Responsable

Tipo de Responsable (*) Tipo de entidad

CIF(*) Nombre (*)

Dirección(*)

Localidad (*)

Provincia(*) CP(*)

Teléfono(*) Fax

e-mail(*) Web

Datos del Fabricante

Nombre o Razón Social (*)

Dirección (*)

Localidad (*)

País(*) República Popular China CP

Teléfono (*) Fax

e-mail (*) Web

Datos de Productos Comunicados

Estatus(*) Primera Comunicación

Relación de Productos

Listado de Productos Sanitarios

Se encontro una fila.

Listado de Productos Sanitarios

Nombre Comercial	Tipo de Producto	Estado del producto	Acción
DISPOSABLE GLOVES (NON-STERILE)	Clase I	Primera Comunicación	

Comentarios

Enviar Solicitud

Agencia Española de Medicamentos y Productos Sanitarios
Parque Empresarial "Las Mercedes", Edif. 8, C/ Campezo 1 - 28022 MADRID | e-Mail: incidencias_aplicaciones@aemps.es

Doc des représentants autorisés de l' Union européenne

CONFIRMATION OF PRODUCT NOTIFICATION

This is to confirm that [redacted] has registered under the AEMPS (Spanish Agency for Medicines and Medical Devices), the following medical devices:

Number in the contract	Product name in English
1	Disposable Gloves (Non-Sterile)

Manufacturer: [redacted]

Address: [redacted]

Registered under number: RPS/[redacted]/2020 (See attached the electronic notification)

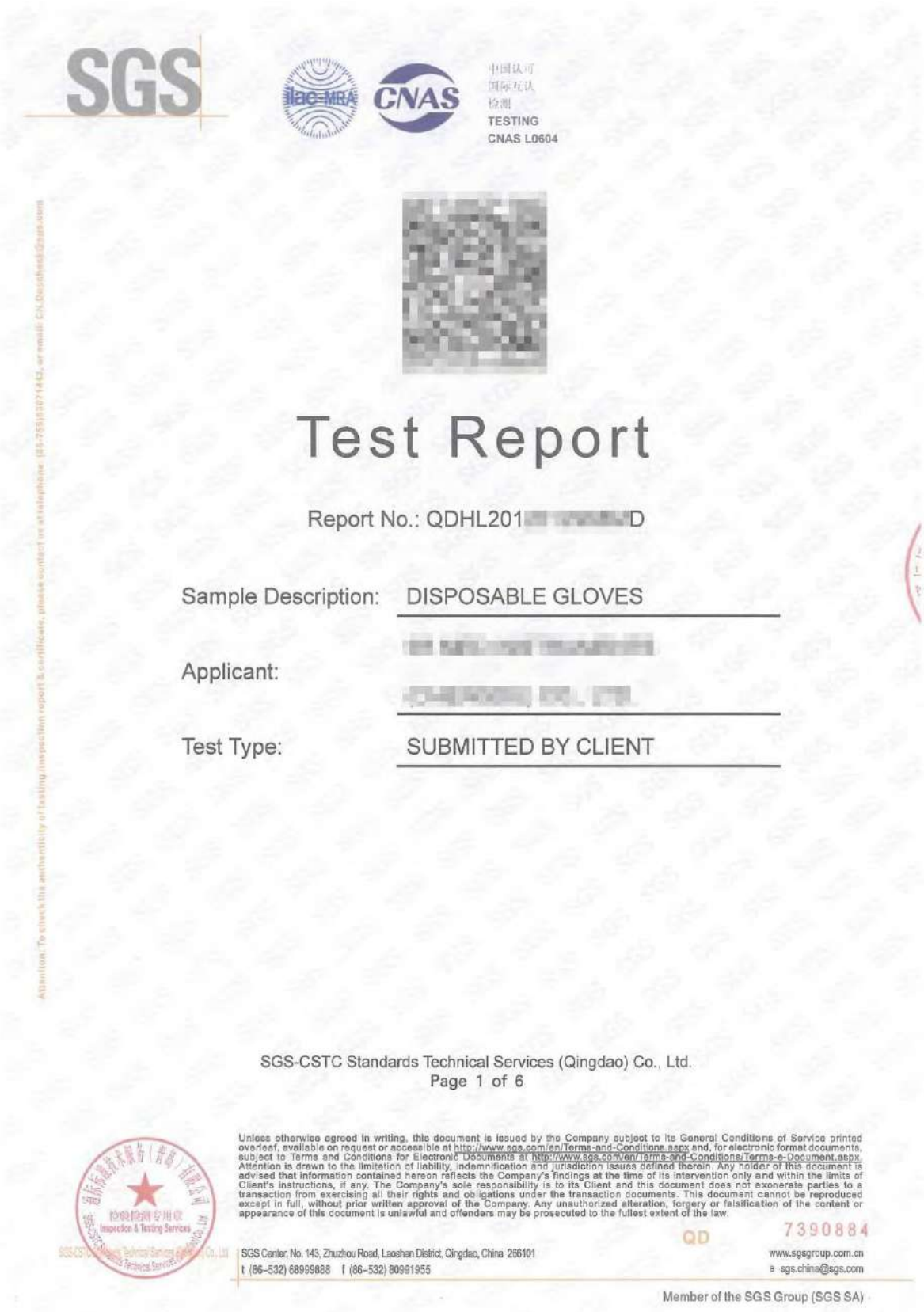
The Manufacturer has declared that these devices comply with the regulation including all the general safety and performance requirements.

[redacted] has complied with its commitment of registering the abovementioned devices under the AEMPS and will not have any other further obligation, compromise or responsibility.

1st July, 2020

Mr. Rubén Valle Ibaseta
On behal of [redacted]

■ SGS Test Report / Nitrile Examination Gloves (EN455-1)



SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Test Report

Report No.: QDHL201 D

Sample Description: DISPOSABLE GLOVES

Applicant:

Test Type: SUBMITTED BY CLIENT

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 1 of 6

QD 7390884

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

TESTING
CNAS L0604

Report No.: QDHL201

Test Report

Sample information	Sample Description	DISPOSABLE GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	200PCS/ 200PCS	Type/ Specifications	5R-GVN(M)
	Lot No.	20201109	Lot Quantity	35000PCS
	Manufacture Date	2020-11-09	Expiration Date	2022-11-08
	Material/Appearance	NITRILE	Storage Condition	HOME TEMPERATURE
	Manufacturer			
Client information	Applicant			
	Applicant address			

QD 7390885

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL20[redacted]

Test information	Sample Receiving Date	DEC.01,2020	Test Period Date	DEC.01,2020 TO DEC.16,2020
	Sample No.	QDHL20[redacted]	Test environment	Meet requirement
	Test items	Water tightness test		
	Testing Accordance	EN 455-1:2020 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes Clause 5.1		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: DEC.16,2020			
Remark	/			

Approver: [signature] Auditor: [signature] Compiler: Lillian Diao

Date: 2020.12.16 Date: 2020.12.16 Date: 2020.12.16

QD 7390886

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

SGS

ilac-MRA CNAS

中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: QDHL20

Sample Photo

QD 7390887

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL20[redacted]

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test	/	EN455-1: 2020 Clause 5.1	Sample quantity: 200pcs AQL: 1.5 Ac: 7 Re: 8	Found: 0	Pass

End of Report

QD 7390888
SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 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; 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

- **Rapport d'essai SGS / Gants d'examen en nitrile(EN455-2)**

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Test Report

Report No.: QDHL20[redacted]

Sample Description: DISPOSABLE GLOVES

Applicant: [redacted]

Test Type: SUBMITTED BY CLIENT

QD 7352535

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

SGS

ILAC-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL[redacted]

Test Report

Sample information	Sample Description	DISPOSABLE GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	80PCS/ 30PCS	Type/ Specifications	GVN(M)/ EXAMINATION/ PROCEDURE GLOVES: b)
	Lot No.	20200926	Lot Quantity	NOT PROVIDED
	Manufacture Date	2020-09-26	Expiration Date	2022-09-25
	Material/Appearance	BUTYRONITRILE	Storage Condition	ROOM TEMPERATURE
	Manufacturer	[redacted]		
Client information	Applicant	[redacted]		
	Applicant address	[redacted]		

QD 7352536

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

SGS

CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL2

Test information	Sample Receiving Date	NOV.04,2020	Test Period Date	NOV.04,2020 TO NOV.06,2020
	Sample No.	QDHL2	Test environment	Meet requirement
	Test items	Dimensions(Length, Width), Tensile strength (Force at break, Force at break after challenge testing)		
	Testing Accordance	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: NOV.06,2020			
Remark	The test results were transferred from test report No. QDHL2010010792MD, Date: NOV.02,2020.			

Approver: JessicaGuo Auditor: JessicaGuo Compiler: Lillian Dzao

Date: 2020.11.06 Date: 2020.11.06 Date: 2020.11.06

QD 7352537

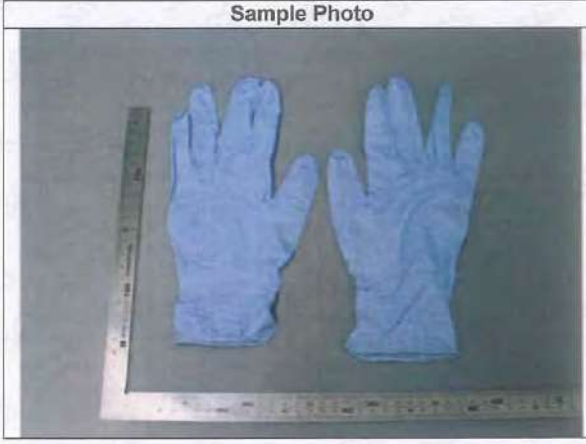
SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

SGS

CNAS
中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: QDHL20

Sample Photo



QD 7352538

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL20[redacted]

Test Results

Test Items		Unit	Test Method	Requirement	Test Result	Assessment
Dimensions	Length	mm	EN 455-2: 2015 clause 4.2	Median value: M: ≥240	See appendix 1 for details	Pass
	Width	mm	EN 455-2: 2015 clause 4.3	Median value: M: 95±10		Pass
Tensile strength	Force at break	N	EN 455-2: 2015 clause 5.2	Median value: ≥6.0	See appendix 2 for details	Pass
	Force at break after challenge testing	N	EN 455-2: 2015 clause 5.3	Median value: ≥6.0		Pass

Appendix 1: Dimensions

Size	M	
No.	Length (mm)	Width (mm)
1	261	98
2	258	98
3	258	98
4	258	98
5	259	98
6	259	98
7	257	97
8	255	98
9	255	98
10	260	98
11	255	98
12	262	98
13	260	98
Standard requirement	≥240	95±10
Median value	258	98

QD 7352539

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL20

Appendix 2: Tensile strength

Size: M			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	9.4	1	8.0
2	8.9	2	7.3
3	9.5	3	7.8
4	8.7	4	7.6
5	8.7	5	7.2
6	9.1	6	9.3
7	9.9	7	9.3
8	8.4	8	9.1
9	7.6	9	7.9
10	7.8	10	7.1
11	7.6	11	8.0
12	8.8	12	7.1
13	7.1	13	7.5
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	8.7	Median value	7.8

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

QD 7352540

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

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; 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

QD 7352541

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

■ Rapport d' essai SGS / Gants d' examen en nitrile(EN455-3)

SGS

Test Report

Report No.: QDHL20[redacted]

Sample Description:	DISPOSABLE GLOVES
Applicant:	[redacted]
Test Type:	SUBMITTED BY CLIENT

Report No.: QDHL200[redacted]

Test Report

Sample information	Sample Description	DISPOSABLE GLOVES	Style/Item No.	5R-GVN
	Received sample quantity/ Tested sample quantity	NOT PROVIDED	Type/Specifications	NOT PROVIDED
	Lot No.	20200926	Lot Quantity	NOT PROVIDED
	Manufacture Date	2020-09-26	Expiration Date	2022-09-25
	Material/Appearance	NOT PROVIDED	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266061
t (86-532) 68999888 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

Report No.: QDHL200[redacted]

Client information	Applicant	[redacted]		
	Applicant address	[redacted] CHINA, [redacted]		
Test information	Sample Receiving Date	SEP.27,2020	Test Period Date	SEP.27,2020 TO OCT.16,2020
	Sample No.	[redacted]	Test environment	Meet requirement
	Test items	Labelling		
	Testing Accordance	EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation Clause 4.6		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: OCT.16,2020			
Remark	/			

Approver: Jessica Gao Auditor: Jessica Gao Compiler: Lillian Diao

Date: OCT.16,2020 Date: OCT.16,2020 Date: OCT.16,2020

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80991055
www.sgsgroup.com.cn
e sgs.china@sgs.com

Report No.: QDHL200

Labelling Artwork

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

Report No.: QDHL20[redacted]

Labelling Artwork (Detail View)

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80991055
www.sgsgroup.com.cn
e sgs.china@sgs.com

Report No.: QDHL20[redacted]

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Labelling	/	EN 455-3:2015	a) The relevant requirement of EN 1041:2008+A1:2013 and EN ISO 15223-1:2012 b) The labelling shall include a prominent indication of whether the glove is powdered or powder-free;	/	Pass

Remarks:

Labelling assessment was based on the information provided by the customer, excluding the verification of the authenticity of the content. SGS is not responsible for verifying the accuracy of the information provided by customers.

End of Report

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266061
t (86-532) 68999888 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

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

- **Rapport d'essai SGS / Gants d'examen en nitrile(FDA ASTM D6319)**

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Test Report

Report No.: QDHL2(

Sample Description: DISPOSABLE GLOVES

Applicant:

Test Type: SUBMITTED BY CLIENT

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 1 of 10

QD 7390266

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL2011[redacted]

Test Report

Sample information	Sample Description	DISPOSABLE GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	S:200PCS, L:100PCS/ S:200PCS, L:35PCS	Type/Specifications	5R-GVN (S/L)
	Lot No.	20201026	Lot Quantity	35000
	Manufacture Date	2020-10-26	Expiration Date	2022-10-25
	Material/Appearance	BUTYRONITRILE	Storage Condition	HOME TEMPERATURE
	Manufacturer	[redacted]		
Client information	Applicant	[redacted]		
	Applicant address	[redacted]		

QD 7390267

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL2011[redacted]

Test information	Sample Receiving Date	NOV.04,2020	Test Period Date	NOV.04,2020 TO NOV.27,2020
	Sample No.	QDHL201[redacted]	Test environment	Meet requirement
	Test items	Freedom from holes (For size S only), Physical dimensions (Length, Width, Thickness) (For size L only), Physical property characteristics (Tensile strength & Ultimate elongation before aging, Tensile strength & Ultimate elongation after aging)(For size L only), Powder residue for powder free gloves (For size L only), Packaging and package marking (For size L only)*		
	Testing Accordance	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application Clause 6.1.2, 6.1.3, 6.1.4, 6.1.5, 9*		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: NOV.27,2020			
Remark	/			

Approver: Jessie Gao Auditor: Jessie Gao Compiler: Lilian Diao

Date: 2020.11.27 Date: 2020.11.27 Date: 2020.11.27

QD 7390268

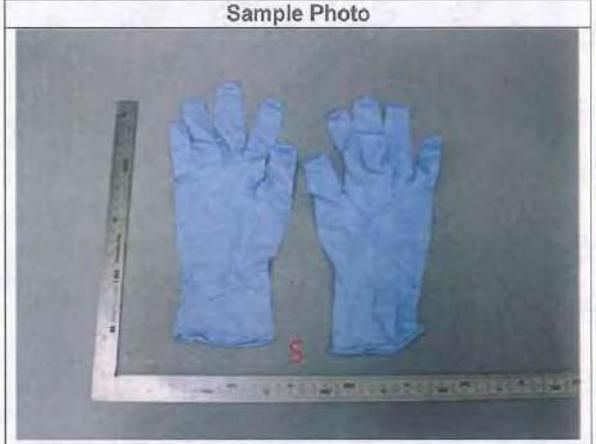
SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

SGS

中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: QDHL201[redacted]

Sample Photo



QD 7390269

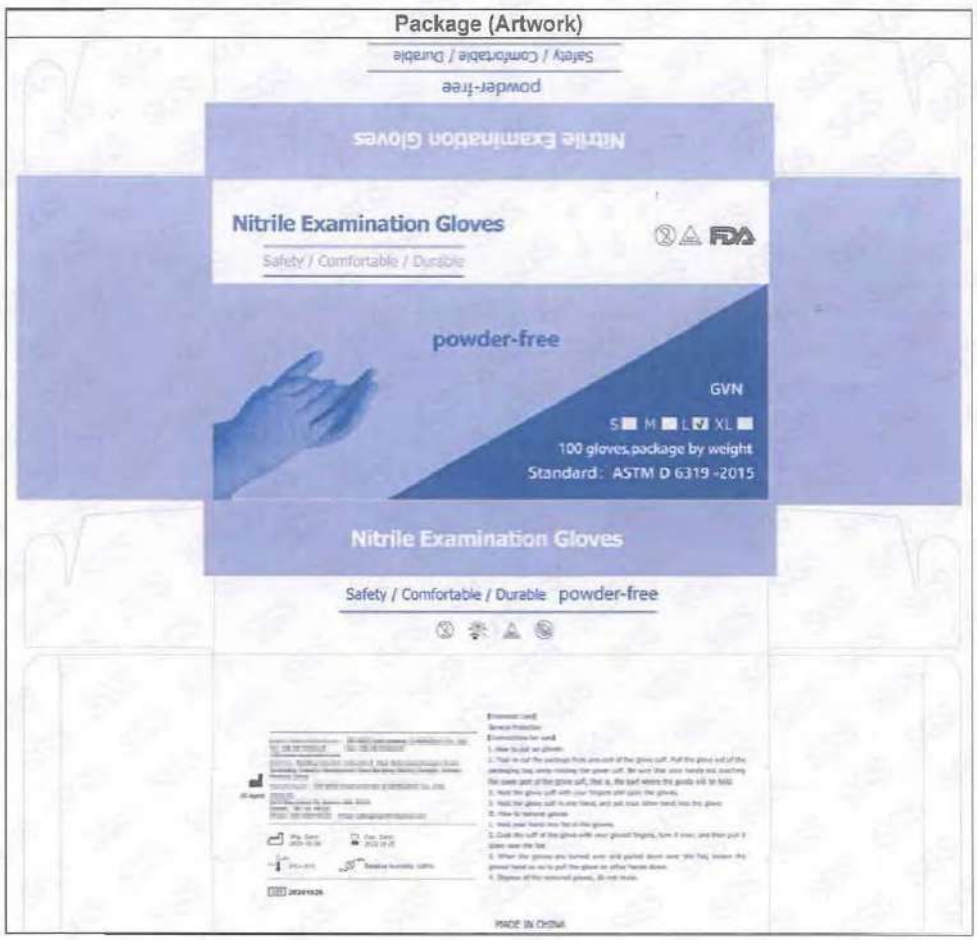
SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

SGS

CNAS
TESTING
CNAS L0604

Report No.: QDHL2011

Package (Artwork)



QD 7390270

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL20110117231MD

Test Results

Test Items			Unit	Test Method	Requirement		Test Result	Assessment
Performance Requirements								
Freedom from Holes			/	ASTM D6319-19 Clause 6.1.2	Sample quantity: S: 200pcs AQL: 2.5 Ac: 10 Re: 11		Found: S: 0	Pass
Physical dimensions	Length		mm	ASTM D6319-19 Clause 6.1.3	L: ≥230	Sample quantity: L:13pcs AQL: 4.0 Ac: 1 Re: 2	See appendix 1 for details	Pass
	Width		mm		L: 110±10			Pass
	Thickness-finger		mm		Median Value:≥0.05			Pass
	Thickness-palm		mm		Median Value:≥0.05			Pass
Physical property characteristics	Before Aging	Tensile strength	MPa	ASTM D6319-19 Clause 6.1.4	≥14	Sample quantity: L:13pcs AQL: 4.0 Ac: 1 Re: 2	See appendix 2 for details	Pass
		Ultimate Elongation	%		≥500			Pass
	After Aging	Tensile strength	MPa		≥14			Pass
		Ultimate Elongation	%		≥400			Pass
Powder Residue For Powder Free Gloves			mg	ASTM D6319-19 Clause 6.1.5	≤2.0	L: 0.80		Pass

QD 7390271

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

SGS

中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: QDHL2011

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Packaging and Package Marking*					
Sterile Packaging	/	ASTM D6319-19 Clause 9.1	See appendix 3 for details	See appendix 3 for details	See appendix 3 for details
Nonsterile and Bulk Packaging	/	ASTM D6319-19 Clause 9.2			
Package Marking	/	ASTM D6319-19 Clause 9.3			

Appendix 1: Physical dimensions

Sample No.	Size: L			
	Length/mm	Width /mm	Median value /mm	
			Thickness-finger	Thickness-palm
1	256	112	0.125	0.096
2	253	113	0.125	0.095
3	254	113	0.137	0.095
4	255	112	0.125	0.094
5	256	113	0.126	0.096
6	257	113	0.124	0.094
7	253	113	0.122	0.094
8	254	113	0.121	0.093
9	258	113	0.124	0.094
10	258	113	0.126	0.098
11	254	113	0.122	0.096
12	256	113	0.122	0.093
13	259	113	0.132	0.097
Standard requirement	≥230	110±10	≥0.05	≥0.05
Found	0	0	0	0

QD 7390272

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL2011011723MD

Appendix 2: Physical property characteristics

Size: L					
Before Aging			After Aging		
Sample No.	Tensile strength (Mpa)	Ultimate Elongation (%)	Sample No.	Tensile strength (Mpa)	Ultimate Elongation (%)
1	21.8	563	1	23.0	498
2	25.5	590	2	14.8	516
3	24.1	521	3	20.9	522
4	20.0	575	4	25.1	531
5	24.1	596	5	21.5	523
6	20.3	574	6	21.5	506
7	23.3	582	7	22.6	513
8	23.8	569	8	23.8	527
9	23.6	567	9	26.3	511
10	22.2	574	10	24.3	509
11	26.2	574	11	23.4	500
12	25.7	549	12	24.5	523
13	24.1	582	13	22.0	509
Standard requirement	≥14	≥500	Standard requirement	≥14	≥400
Found	0	0	Found	0	0

QD 7390273

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL2011011723MD

Appendix 3: Packaging and Package Marking

Contents specified in the standard		Conformity	Regulatory requirements	Comments
1 Sterile Packaging		Not applicable	ASTM D6319-19 9.1	/
2 Nonsterile and Bulk Packaging				
2.1	The gloves shall be enclosed in an outer package that has sufficient strength to withstand normal transportation and storage within the cartons or shipping cases, or both.	Not conducted	ASTM D6319-19 9.2.1	No outer package was provided
2.2	None of the packaging material shall contain any material likely to impair the quality and use of the gloves.	Pass	ASTM D6319-19 9.2.2	No visible damage was found on gloves.
2.3	Cartons and shipping cases shall be of sufficient strength to maintain the quality of the product during normal transportation and storage.	Not conducted	ASTM D6319-19 9.2.3	No cartons and shipping cases were provided.
3 Package Marking				
3.1	Sterile packages shall bear markings for the contents to include the glove size, instructions for opening, the legend "sterile," and a manufacturing lot number.	Not applicable	ASTM D6319-19 9.3.1	Non-sterile
3.2	Nonsterile and bulk packages shall bear markings for the contents to include the glove size and a manufacturing lot number.	Pass	ASTM D6319-19 9.3.2	Glove size: L. Lot number: 20201026
3.3	The outermost case shall be labeled with the glove size and a manufacturing lot number. Sterile product cases shall also be marked with the legend "sterile."	Not conducted	ASTM D6319-19 9.3.3	No outermost case was provided.
3.4	All levels of packaging shall conform to all appropriate government labeling regulations.	Pass	ASTM D6319-19 9.3.4	/

Remarks:
1. * Test items were not included in the CNAS accredited schedule for our laboratory.
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
3. Packaging and Package Marking assessment was based on the information provided by the customer, excluding the verification of the authenticity of the content. SGS is not responsible for verifying the accuracy of the information provided by customers.

End of Report

QD 7390274

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999688 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 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; 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

QD 7390275

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

■ ■ Rapport d' essai CTC / Gants jetables en nitrile (EN420+EN374-5)

CTC
SHANGHAI
3F, Building Block 2, No. 3400 Gonghexin Road,
Jing'an District - Shanghai 200436, P.R. CHINA
上海市静安区共和新路3400号2幢3层
Tél. : +86 21 68 55 50 32
Fax : +86 21 68 55 50 33
E-mail : ctcshanghai@ctcgroupe.com

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

TEST REPORT

Report No.: [redacted]

03 February 2021

APPLICANT: [redacted]

1764336324@qq.com

Date of receipt :26 Jan. 2021
Testing period :28 Jan. 2021
:29 Jan. 2021

Buyer: —

Sample description: EN ISO 374-5:2016

Reference no. :S, M, L, XL
Style / Article no. : [redacted]
Test(s) requested :—
Service :REGULAR
Brand / Section :—
Season :—
End use :Disposable Gloves
Factory name :—
Factory code :—
Revision :Amend sample information.

For CE Marking : Yes
Previous report :—
Product category :—
Product type :—
Test stage :FIRST TEST
Supplier name :—
Exported to :—

1. Conclusion:

	Tests description	Conformity
1	4.2. Aromatic amines derived from azo colorants : ISO 14362-1:2017 (w/o extraction)	Pass
2	4.2. pH - Textile (KCl solution) : ISO 3071:2020	Pass
3	4.2. Polycyclic Aromatic Hydrocarbons (8) : ISO/TS 16190: 2013	Pass
4	5.2. Dexterity : EN ISO 21420: 2020	Level 5
5	Air Leak Test : EN ISO 374-2:2019	Pass
6	Water Leak Test : EN ISO 374-2:2019	Pass

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable

Approved by

Henry YAN 严滨
Laboratory Manager

Yvonne MAO 茅璇怡
Senior Analytical Chemical Engineer

This test report in version S210100683_2 supersedes the report S210100683_1

CTC SHANGHAI

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

TEST REPORT

Report No.: [redacted] 03 February 2021

APPLICANT: [redacted]

2. Sample(s) description assigned by laboratory:

Size	Analyzed product	Description	Sample information
	GLOVE		
		Whole glove	
		blue nitrile palm(glove)	

210100683

CTC SHANGHAI

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

TEST REPORT

Report No.: [redacted] 03 February 2021

APPLICANT: [redacted]

3. GLOVE/

Whole glove

	Method	Client Requirement	Unit	Result	Conformity
5.2. Dexterity	EN ISO 21420: 2020				
Smallest diameter of pin fulfilling test condition			mm	5.0	
Smallest diameter of pin fulfilling test condition (2)			mm	5.0	
Smallest diameter of pin fulfilling test condition (3)			mm	5.0	
Smallest diameter of pin fulfilling test condition (4)			mm	5.0	
Performance level				5	
• Air Leak Test	EN ISO 374-2:2019				Pass
Glove thickness			mm	0.07	
Air pressure used to test			kPa	2.5	
Result		No air bubbles		No air bubbles	
• Water Leak Test	EN ISO 374-2:2019				Pass
Result		No water leak		No water leak	

blue nitrile palm(glove)

	Method	Client Requirement	Unit	Result	Conformity
(+) **4.2. pH - Textile (KCl solution)**	ISO 3071:2020				Pass
pH value		3.5< - <9.5		7.9	
4.2. Aromatic amines derived from azo colorants	ISO 14362-1:2017 (w/o extraction)				Pass
Accessible without fibre extraction		<30	mg/kg	<5	
▲4.2. Polycyclic Aromatic Hydrocarbons (8)	ISO/TS 16190: 2013				Pass
Benzo(a)anthracene		<1	mg/kg	<0.1	
Chrysene		<1	mg/kg	<0.1	
Benzo(b)fluoranthene		<1	mg/kg	<0.1	
Benzo(k)fluoranthene		<1	mg/kg	<0.1	
Benzo(a)pyrene		<1	mg/kg	<0.1	
Dibenzo(a,h)anthracene		<1	mg/kg	<0.1	
Benzo(e)pyrene		<1	mg/kg	<0.1	
Benzo(j)fluoranthene		<1	mg/kg	<0.1	

This test report in version S210100683_2 supersedes the report S210100683_1

To declare the conformity to the requirement, the uncertainty of measurement, associated to the test results, has not been taken into account.

CTC SHANGHAI

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

TEST REPORT

Report No.: [redacted] 03 February 2021

APPLICANT: [redacted]

END OF TEST REPORT

(+)CNAS accreditation

▲: The test was carried out by external accredited laboratory under their accreditation scope.
●: The test was carried out by external accredited laboratory, not within their accreditation scope.

Unless otherwise specified, the physical test items in this report performed in CTC Shanghai lab were conditioned and tested in the environment of T 23±2°C / RH 50±4%.

Table of Performance Level for Glove

Test Item	Performance Level					
	0##	1	2	3	4	5
Finger dexterity (EN ISO 21420) Smallest diameter of pin fulfilling test conditions (mm)	---	11.0	9.5	8.0	6.5	5.0

Performance level 0 means the glove falls below the minimum performance level for the given individual hazard

Rapport d' essai CTT / Gants jetables en nitrile (GB4806.11)

CTT CONSUMER TESTING TECH

CMA 201819001289 ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L3068

Test Report

Report No.: [redacted] Page 1 of 3

Applicant: [redacted]
Address: [redacted]

Sample Received Date: Oct. 12, 2020
Completed Date: Oct. 16, 2020
Report Date: Oct. 22, 2020

The following merchandise was (were) submitted and identified on behalf of the applicant as:
Sample Name: Disposable Gloves
Model No.: L 、S、M、XL

Test Result(s): Please refer to next page(s).

Test Requested and Conclusion(s):

No.	Standard and Requirement	Conclusion(s)
1	GB 4806.7-2016 National food safety standard plastic materials and products for food contact - Sensory requirements	PASS
2	GB 4806.11-2016: National Food Safety Standard Food contact rubber articles. - Heavy metal (express as Pb) - Potassium permanganate consumption	PASS

Organization: wan ting. Wu To examine: Tony

Signed for and on Behalf of CTT:

Hilary He

Hilary He
Technical Manager

Consumer Testing Technology Co., Ltd. Click For Authentication

Dongguan Consumer Testing Technology Co., Ltd.
No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: http://www.cttlab.com Email: enquiry@cttlab.com

Test Report

Report No.: [redacted]

Test Result(s):

Sensory requirements - GB 4806.7-2016：National Food Safety Standard Food contact plastic articles

Method: GB 4806.7-2016

Material No.	Test Item	Requirement	Result	Conclusion
1	Sensory	Color of outlook is normal, no foreign smell, no foreign matter.	Color of outlook is normal, no foreign smell, no foreign matter.	PASS
	Soaking solution	Migration of solution should clear, no bad smell, no foreign smell	Migration of solution clear, no bad smell, no foreign smell	PASS

Test Result(s):

Heavy metal (express as Pb) - GB 4806.11-2016：National Food Safety Standard Food contact rubber articles.

Method: GB 31604.9-2016

Material No.	Test Item	Reporting Limit (mg/kg)	Limit (mg/kg)	Result (mg/kg)	Conclusion
1	Heavy metal (express as Pb)	1	1	N.D.	PASS

NOTE:
1. mg/kg = milligram per kilogram (ppm).
2. N.D. = Not Detected (Less than Reporting Limit).
3. Test condition: 4% Acetic acid(v/v), 60℃, 0.5hour.

Test Result(s):

Potassium permanganate consumption - GB 4806.11-2016：National Food Safety Standard Food contact rubber articles.

Method: GB 31604.2-2016

Material No.	Test Item	Reporting Limit (mg/kg)	Limit (mg/kg)	Result (mg/kg)	Conclusion
1	Potassium permanganate consumption	1	10	N.D.	PASS

NOTE:
1. mg/kg = milligram per kilogram (ppm).
2. N.D. = Not Detected (Less than Reporting Limit).
3. Test condition: distilled water, 60℃, 0.5hour.

Dongguan Consumer Testing Technology Co., Ltd.
No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: http://www.cttlab.com Email: enquiry@cttlab.com

Test Report

Report No.: [redacted]

Test Material List

Material No.	Sample Description	Location
1	Blue rubber	Gloves

Remark: This report supersedes CTT2010010616EN which is withdrawn.

Photo of Sample:

End of Report

Dongguan Consumer Testing Technology Co., Ltd.
No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: http://www.cttlab.com Email: enquiry@cttlab.com

CTT CONSUMER TESTING TECH

CMA 201819001289 ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L3068

检测报告

报告编号： [redacted] 第 1 页 共 3 页

申请单位： [redacted]
地　　址： [redacted]

收样日期： 2020 年 10 月 12[redacted]
完成日期： 2020 年 10 月 16 日
报告日期： 2020 年 10 月 22 日

以下检测样品信息是由申请者所提供及确认：
样品名称： 一次性使用手套
样品型号： L 、S、M、XL

检测结果： 请参见下页。

检测要求和结论：

序号	标准和要求	结论
1	GB 4806.7-2016 食品安全国家标准 食品接触用塑料材料及制品 - 感官要求	合格
2	GB 4806.11-2016：食品安全国家标准 食品接触用橡胶材料及制品 - 重金属（以铅计） - 高锰酸钾消耗量	合格

编制：[redacted] 审核：[redacted]

授权签字人：
中鼎检测机构

何晓莹

何晓莹
技术经理

点击查伪

东莞市中鼎检测技术有限公司
广东省东莞市松山湖高新技术产业开发区工业北四路 7 号
电话：86-0769-8898 9888　传真：86-0769-8898 8808　热线：400 6789 666
网址：http://www.cttlab.com　邮箱：enquiry@cttlab.com

检测报告

报告编号：[redacted]　　第 2 页　共 3 页

检测结果：

感官要求 - GB 4806.7-2016：食品安全国家标准 食品接触用塑料材料及制品

方法：GB 4806.7-2016

材料编号	测试项目	要求	结果	单项判定
1	感官	色泽正常，无异臭、不洁物等。	色泽正常，无异臭、不洁物等	合格
	浸泡液	迁移试验所得浸泡液无浑浊、沉淀、异臭等感官性的劣变。	迁移试验所得浸泡液无浑浊、沉淀、异臭等感官性的劣变	合格

检测结果：

重金属（以铅计） - GB 4806.11-2016：食品安全国家标准 食品接触用橡胶材料及制品

方法：GB 31604.9-2016

材料编号	检测项目	报告限值 (mg/kg)	限值 (mg/kg)	结果 (mg/kg)	单项判定
1	重金属（以铅计）	1	1	N.D.	合格

注释：　1、mg/kg = 毫克每千克(ppm)。
2、N.D. = 未检测到(小于报告限值)。
3、测试条件：4% 醋酸(v/v)，60℃，0.5 小时。

检测结果：

高锰酸钾消耗量 - GB 4806.11-2016：食品安全国家标准 食品接触用橡胶材料及制品

方法：GB 31604.2-2016

材料编号	检测项目	报告限值 (mg/kg)	限值 (mg/kg)	结果 (mg/kg)	单项判定
1	高锰酸钾消耗量	1	10	N.D.	合格

注释：　1、mg/kg = 毫克每千克(ppm)。
2、N.D. = 未检测到(小于报告限值)。
3、测试条件：蒸馏水，60℃，0.5 小时。

东莞市中鼎检测技术有限公司
广东省东莞市松山湖高新技术产业开发区工业北四路 7 号
电话：86-0769-8898 9888　传真：86-0769-8898 8808　热线：400 6789 666
网址：http://www.cttlab.com　邮箱：enquiry@cttlab.com

检测报告

报告编号：[redacted]

测试材料清单

材料编号	样品描述	位置
1	蓝色橡胶	手套

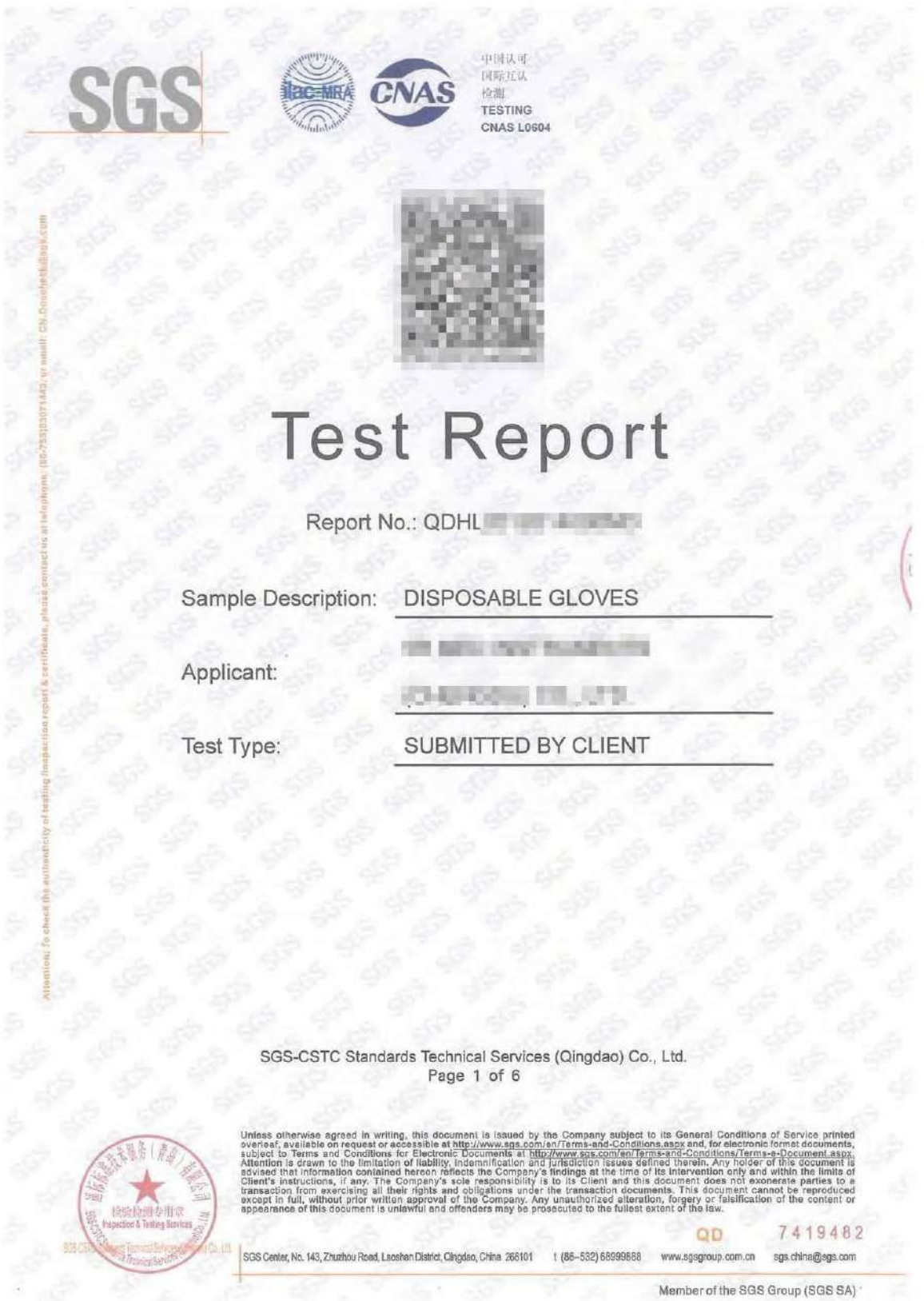
备注：本报告代替 CTT2010010616CN 检测报告，原报告作废。

样品照片：

报告完

东莞市中鼎检测技术有限公司
广东省东莞市松山湖高新技术产业开发区工业北四路 7 号
电话：86-0769-8898 9888 传真：86-0769-8898 8808 热线：400 6789 666
网址：http://www.cttlab.com 邮箱：enquiry@cttlab.com

- **SGS Test Report——Vinyl Examination Gloves (CE EN455-1)**



SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Test Report

Report No.: QDHL

Sample Description: DISPOSABLE GLOVES

Applicant:

Test Type: SUBMITTED BY CLIENT

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 1 of 6

QD 7419482

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL2[illegible]

Test Report

Sample information	Sample Description	DISPOSABLE GLOVES	Color	WHITE
	Received sample quantity/ Tested sample quantity	300PCS/ 200PCS	Type/ Specifications	5R-GVC(L)
	Lot No.	20201224	Lot Quantity	35000
	Manufacture Date	2020-12-24	Expiration Date	2022-12-23
	Material/Appearance	PVC	Storage Condition	HOME TEMPERATURE
	Manufacturer	[illegible]		
Client information	Applicant	[illegible]		
	Applicant address	[illegible]		

QD 7419483

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101 t (86-532) 68999898 www.sgsgroup.com.cn sgs.china@sgs.com

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL20[redacted]

Test information	Sample Receiving Date	DEC.30,2020	Test Period Date	DEC.30,2020 TO JAN.15,2021
	Sample No.	QDHL2012014000MD	Test environment	Meet requirement
	Test items	Water tightness test		
	Testing Accordance	EN 455-1:2020 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes Clause 5.1		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: JAN.15,2021			
Remark	/			

Approver: Auditor: Compiler:

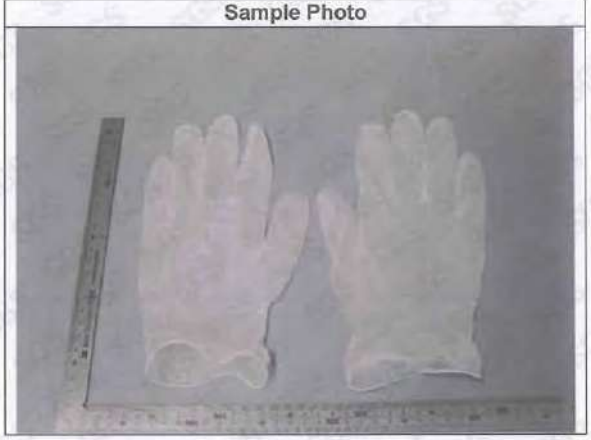
Date: 2021.01.15 Date: 2021.01.15 Date: 2021.01.15

SGS

中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: [redacted]

Sample Photo



SGS

中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: QDHL20120[redacted]

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test	/	EN 455-1: 2020 Clause 5.1	Sample quantity: 200 pcs AQL: 1.5 Ac: 7 Re: 8	Found: 0	Pass

End of Report

QD 7419486

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 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; 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.

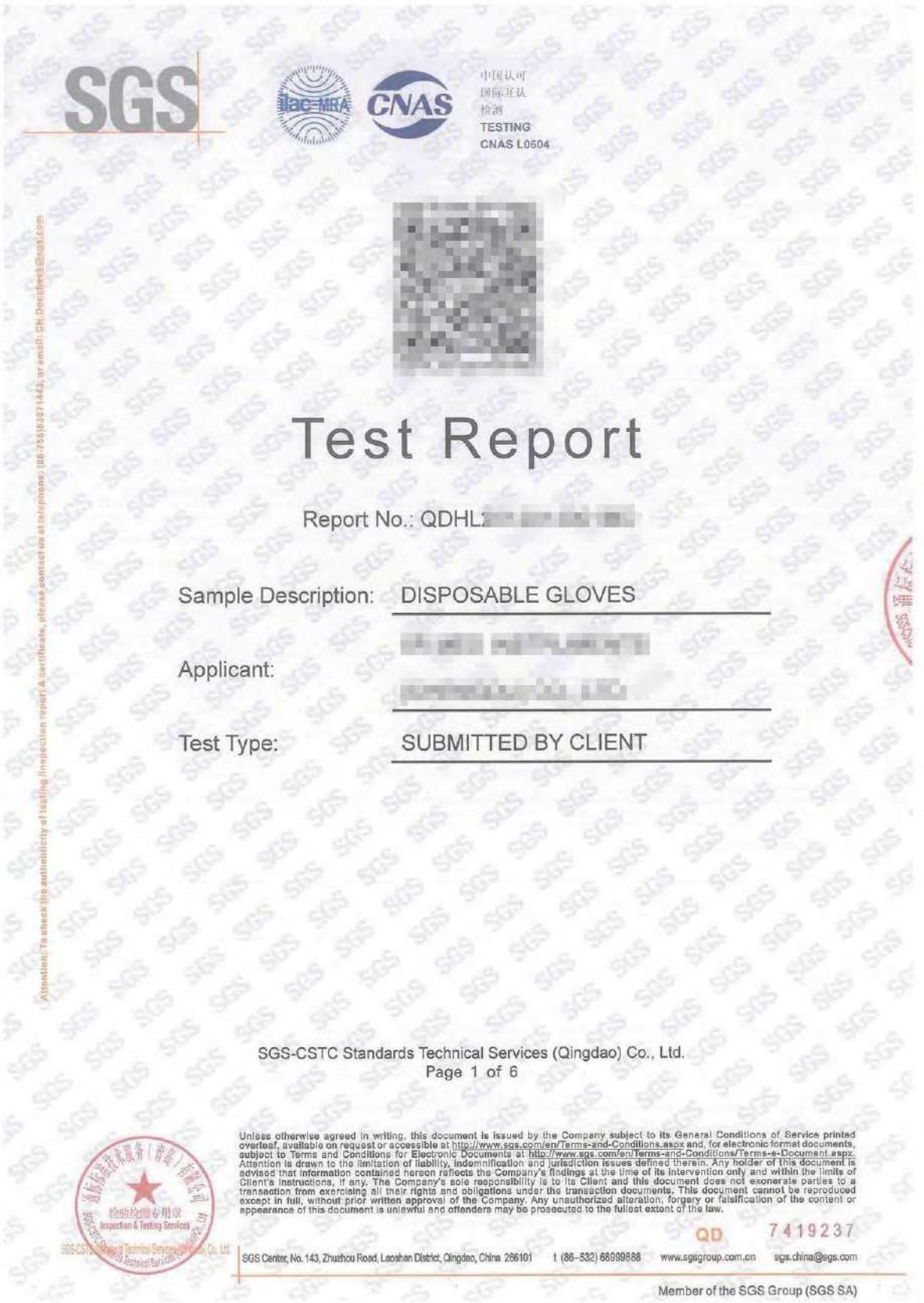
5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

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

- **Rapport d'essai SGS / Gants d'examen en vinyle(CE EN455-3)**



SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Test Report

Report No.: QDHL[redacted]

Sample Description: DISPOSABLE GLOVES

Applicant: [redacted]

Test Type: SUBMITTED BY CLIENT

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Page 1 of 6

QD 7419237

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL201[redacted]

Test Report

Sample information	Sample Description	DISPOSABLE GLOVES	Color	WHITE
	Received sample quantity/ Tested sample quantity	50PCS/ 5PCS	Type/ Specifications	5R-GVC (L)
	Lot No.	20201224	Lot Quantity	35000
	Manufacture Date	2020-12-24	Expiration Date	2022-12-23
	Material/Appearance	PVC	Storage Condition	HOME TEMPERATURE
	Manufacturer	[redacted]		
Client information	Applicant	[redacted]		
	Applicant address	[redacted]		

QD 7419238

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL[redacted]

Test information	Sample Receiving Date	DEC.30,2020	Test Period Date	DEC.30,2020 TO JAN.06,2021
	Sample No.	[redacted]	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: JAN.06,2021			
Remark	/			

Approver: Jessica Luo Auditor: Jessica Luo Compiler: Lillian Diao

Date: 2021.01.06 Date: 2021.01.06 Date: 2021.01.06

QD 7419239

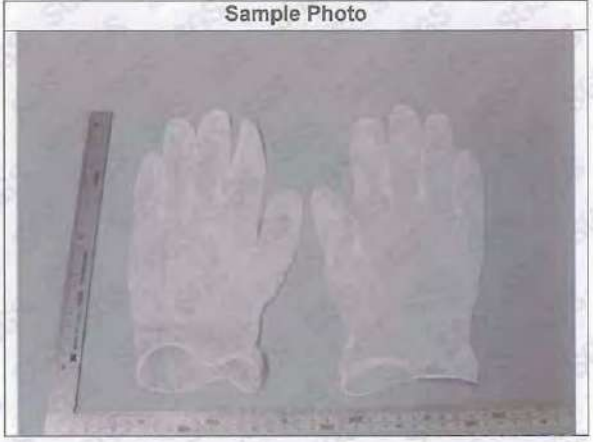
SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com

SGS

中国认可
国际互认
检测
TESTING
CNAS L0604

Report No.: QDHL20

Sample Photo



QD 7419240

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

SGS

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L0604

Report No.: QDHL20[redacted]

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Removable surface powder	mg	EN 455-3: 2015 Clause 4.4 EN ISO 21171: 2006	≤2	0.14	Pass

Remarks:

(1) Finishes of gloves: Powdered-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

QD 7419241

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

SGS

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; 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

CTC Test Report / Disposable Vinyl Gloves(EN ISO 21420+EN ISO 374-5)

CTC
SHANGHAI
3F, Building Block 2, No. 3400 Gonghexin Road,
Jing'an District - Shanghai 200436, P.R. CHINA
上海市静安区共和新路3400号2幢3层
Tel. : +86 21 68 55 50 32
Fax : +86 21 68 55 50 33
E-mail : ctcshanghai@ctcgroupe.com

TEST REPORT

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

Report No.: [redacted] 14 September 2020

APPLICANT: [redacted]

Date of receipt :09 Sept. 2020
Testing period :10 Sept. 2020
:14 Sept. 2020

Buyer: —

Sample description: EN ISO 374-5:2016

Reference no. :S, M, L, XL
Style / Article no. : [redacted]
Test(s) requested :—
Service :REGULAR
Brand / Section :—
Season :—
End use :Disposable Gloves
Factory name :—
Factory code :—

For CE Marking : Yes
Previous report :—
Product category :—
Product type :—
Test stage :FIRST TEST
Supplier name :—
Exported to :—

1. Conclusion:

	Tests description	Conformity
	EN ISO 21420/EN ISO 374-1	
1	pH - Textile (KCl solution)	Pass
2	Aromatic amines derived from azo colorants	Pass
3	Polycyclic Aromatic Hydrocarbons (8)	Pass
4	Dexterity	Level 5
5	Air Leak Test	Pass
6	Water Leak Test	Pass

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable

Approved by

Henry YAN
Laboratory Manager

Yvonne MAO
Senior Analytical Chemical Engineer

CTC SHANGHAI

TEST REPORT

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

Report No.: [redacted] 14 September 2020

APPLICANT: [redacted]

2. Sample(s) description assigned by laboratory:

Size	Analyzed product	Description	Sample information
	GLOVE		
		Whole glove	
		white vinyl palm	

CTC SHANGHAI

TEST REPORT

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

Report No.: [redacted] 14 September 2020

APPLICANT: [redacted]

3. GLOVE/

Whole glove

	Method	Client Requirement	Unit	Result	Conformity
5.2. Dexterity	EN ISO 21420: 2020				
Smallest diameter of pin fulfilling test condition			mm	5.0	
Smallest diameter of pin fulfilling test condition (2)			mm	5.0	
Smallest diameter of pin fulfilling test condition (3)			mm	5.0	
Smallest diameter of pin fulfilling test condition (4)			mm	5.0	
Performance level				5	
• Air Leak Test	EN 374-2:2019				Pass
Glove thickness			mm	0.10	
Air pressure used to test			kPa	3.5	
Result		No air bubbles		No air bubbles	
• Water Leak Test	EN 374-2:2019				Pass
Result		No water leak		No water leak	

white vinyl palm

	Method	Client Requirement	Unit	Result	Conformity
(+) **4.2. pH - Textile (KCl solution)**	ISO 3071:2020				Pass
pH value		3.5< - <9.5		7.3	
4.2. Aromatic amines derived from azo colorants	ISO 14362-1:2017 (w/o extraction)				Pass
Accessible without fibre extraction		<30	mg/kg	<5	
▲ 4.2. Polycyclic Aromatic Hydrocarbons (8)	ISO/TS 16190: 2013				Pass
Benzo(a)anthracene		<1	mg/kg	<0.1	
Chrysene		<1	mg/kg	<0.1	
Benzo(b)fluoranthene		<1	mg/kg	<0.1	
Benzo(k)fluoranthene		<1	mg/kg	<0.1	
Benzo(a)pyrene		<1	mg/kg	<0.1	
Dibenzo(a,h)anthracene		<1	mg/kg	<0.1	

CTC SHANGHAI

TEST REPORT

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

Report No.: [redacted] 14 September 2020

APPLICANT: [redacted]

	Method	Client Requirement	Unit	Result	Conformity
Benzo(e)pyrene		<1	mg/kg	<0.1	
Benzo(j)fluoranthene		<1	mg/kg	<0.1	

END OF TEST REPORT

(+)CNAS accreditation

▲: The test was carried out by external accredited laboratory under their accreditation scope.
●: The test was carried out by external accredited laboratory, not within their accreditation scope.

Table of Performance Level for Glove

Test Item	Performance Level					
	0##	1	2	3	4	5
Finger dexterity (EN ISO 21420) Smallest diameter of pin fulfilling test conditions (mm)	---	11.0	9.5	8.0	6.5	5.0

Performance level 0 means the glove falls below the minimum performance level for the given individual hazard

- **Rapport d'essai CTT / Gants en vinyle jetables (GB4806.7)**

CTT

CMA 201819001289 ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L3068

Test Report

Report No.: C [redacted] Page 1 of 3

Applicant: [redacted]
Address: [redacted]

Sample Received Date: Aug. 13, 2020
Completed Date: Aug. 17, 2020
Report Date: Aug. 18, 2020

The following merchandise was (were) submitted and identified on behalf of the applicant as:
Sample Name: Disposable Gloves
Model No.: L、S、M、XL
Brand:

Test Result(s): Please refer to next page(s).

Test Requested and Conclusion(s):

No.	Standard and Requirement	Conclusion(s)
1	GB 4806.7-2016 National food safety standard plastic materials and products for food contact - Overall Migration - Heavy metal (express as Pb) - Potassium permanganate consumption	PASS

Organization: Jun. Zhao To examine: Tony

Signed for and on Behalf of CTT:

Hilary He

Hilary He
Technical Manager

Consumer Testing Technology Co., Ltd. Click For Authentication

Dongguan Consumer Testing Technology Co., Ltd.
No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: http://www.cttlab.com Email: enquiry@cttlab.com

Test Report

Report No.: [redacted]

Test Result(s):

Overall Migration - GB 4806.7-2016：National Food Safety Standard Food contact plastic articles

Method: GB 31604.8-2016

Material No.	Test Condition	Reporting Limit (mg/dm²)	Limit (mg/dm²)	Result (mg/dm²)	Conclusion
001	4% Acetic acid(v/v) ,70℃ ,2h	3	10	N.D.	PASS

NOTE: 1. mg/dm²= milligram per square decimeter.
2. N.D. = Not Detected (Less than Reporting Limit).

Test Result(s):

Heavy metal (express as Pb) - GB 4806.7-2016：National Food Safety Standard Food contact plastic articles

Method: GB 31604.9-2016

Material No.	Test Item	Reporting Limit (mg/kg)	Limit (mg/kg)	Result (mg/kg)	Conclusion
001	Heavy metal (express as Pb)	1	1	N.D.	PASS

NOTE: 1. mg/kg = milligram per kilogram (ppm).
2. N.D. = Not Detected (Less than Reporting Limit).
3. Test condition: 4% Acetic acid(v/v), 60℃, 2 hours.

Test Result(s):

Potassium permanganate consumption - GB 4806.7-2016：National Food Safety Standard Food contact plastic articles

Method: GB 31604.2-2016

Material No.	Test Item	Reporting Limit (mg/kg)	Limit (mg/kg)	Result (mg/kg)	Conclusion
001	Potassium permanganate consumption	1	10	N.D.	PASS

NOTE: 1. mg/kg = milligram per kilogram (ppm).
2. N.D. = Not Detected (Less than Reporting Limit).
3. Test condition: distilled water, 60℃, 2 hours.

Dongguan Consumer Testing Technology Co., Ltd.
No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: http://www.cttlab.com Email: enquiry@cttlab.com

Test Report

Report No.: [redacted]

Test Material List

Material No.	Sample Description	Location
001	White translucent plastic	Gloves

Photo of Sample:

End of Report

Dongguan Consumer Testing Technology Co., Ltd.
No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: http://www.cttlab.com Email: enquiry@cttlab.com

CTT CONSUMER TESTING TECH

CMA 201819001289 ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L3068

检测报告

报告编号： [redacted]N　　第 1 页　共 3 页

申请单位： [redacted]
地　　址： [redacted]

收样日期： 2020 年 08 月 13 日
完成日期： 2020 年 08 月 17 日
报告日期： 2020 年 08 月 18 日

以下检测样品信息是由申请者所提供及确认：
样品名称： 一次性使用手套
样品型号： L、S、M、XL
商标：

检测结果：请参见下页。
检测要求和结论：

序号	标准和要求	结论
1	GB 4806.7-2016 食品安全国家标准 食品接触用塑料材料及制品 - 总迁移量 - 重金属（以铅计） - 高锰酸钾消耗量	合格

编制：赵果　　审核：

授权签字人：
中鼎检测机构

何晓莹
技术经理

点击查伪

东莞市中鼎检测技术有限公司
广东省东莞市松山湖高新技术产业开发区工业北四路 7 号
电话：86-0769-8898 9888　传真：86-0769-8898 8808　热线：400 6789 666
网址：http://www.cttlab.com　邮箱：enquiry@cttlab.com

检测报告

报告编号：[redacted]　　第 2 页　共 3 页

检测结果：

总迁移量 - GB 4806.7-2016：食品安全国家标准食品接触用塑料材料及制品

方法：GB 31604.8-2016

材料编号	检测条件	报告限值 (mg/dm²)	限值 (mg/dm²)	结果 (mg/dm²)	单项判定
001	4% 乙酸（v/v） ,70℃ ,2h	3	10	N.D.	合格

注释：　1、mg/dm²=毫克每平方分米。
2、N.D. = 未检测到(小于报告限值)。

检测结果：

重金属（以铅计） - GB 4806.7-2016：食品安全国家标准食品接触用塑料材料及制品

方法：GB 31604.9-2016

材料编号	检测项目	报告限值 (mg/kg)	限值 (mg/kg)	结果 (mg/kg)	单项判定
001	重金属（以铅计）	1	1	N.D.	合格

注释：　1、mg/kg = 毫克每千克(ppm)。
2、N.D. = 未检测到(小于报告限值)。
3、测试条件：4% 乙酸(v/v)，60℃，2h。

检测结果：

高锰酸钾消耗量 - GB 4806.7-2016：食品安全国家标准食品接触用塑料材料及制品

方法：GB 31604.2-2016

材料编号	检测项目	报告限值 (mg/kg)	限值 (mg/kg)	结果 (mg/kg)	单项判定
001	高锰酸钾消耗量	1	10	N.D.	合格

注释：　1、mg/kg = 毫克每千克(ppm)。
2、N.D. = 未检测到(小于报告限值)。
3、测试条件：蒸馏水，60℃，2h。

测试材料清单

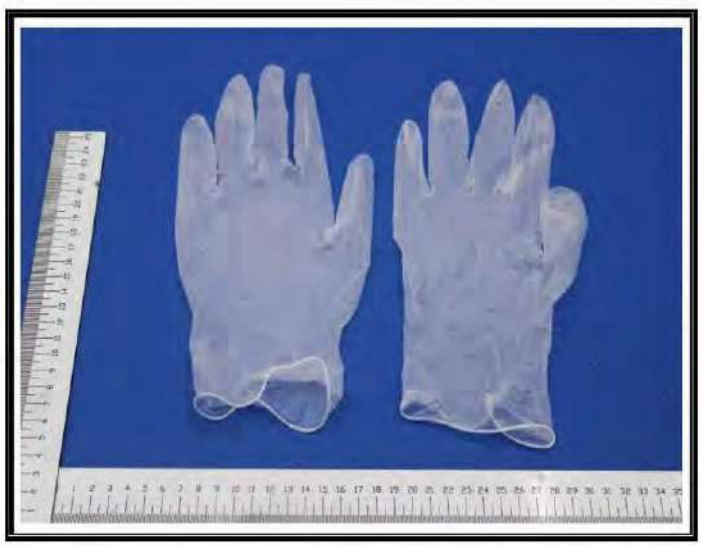
材料编号	样品描述	位置
001	白色半透明塑胶	手套

东莞市中鼎检测技术有限公司
广东省东莞市松山湖高新技术产业开发区工业北西路 7 号
电话：86-0769-8898 9888　传真：86-0769-8898 8808　热线：400 6789 666
网址：http://www.cttlab.com　邮箱：enquiry@cttlab.com

检测报告

报告编号：[redacted]

样品照片：



报告完

东莞市中鼎检测技术有限公司
广东省东莞市松山湖高新技术产业开发区工业北四路 7 号
电话：86-0769-8898 9888 传真：86-0769-8898 8808 热线：400 6789 666
网址：http://www.cttlab.com 邮箱：enquiry@cttlab.com

- **Rapport d'essai CTC——Gants de protection synthétiques(EN ISO 21420+EN ISO 374-5)**

CTC SHANGHAI
3F, Building Block 2, No. 3400 Gonghexin Road,
Jing'an District - Shanghai 200436, P.R. CHINA
上海市静安区共和新路3400号2幢3层
Tél. : +86 21 68 55 50 32
Fax : +86 21 68 55 50 33
E-mail : ctcshanghai@ctcgroupe.com

TEST REPORT

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

Report No.: [redacted] 14 September 2020

APPLICANT: [redacted]

Date of receipt :09 Sept. 2020
Testing period :10 Sept. 2020
:14 Sept. 2020

Buyer: —

Sample description: EN ISO 374-5:2016

Reference no. :S, M, L, XL
Style / Article no. : [redacted]
Test(s) requested :—
Service :REGULAR
Brand / Section :—
Season :—
End use :Disposable Gloves
Factory name :—
Factory code :—

For CE Marking : Yes
Previous report :—
Product category :—
Product type :—
Test stage :FIRST TEST
Supplier name :—
Exported to :—

1. Conclusion:

	Tests description	Conformity
	EN ISO 21420/EN ISO 374-1	
1	pH - Textile (KCl solution)	Pass
2	Aromatic amines derived from azo colorants	Pass
3	Polycyclic Aromatic Hydrocarbons (8)	Pass
4	Dexterity	Level 5
5	Air Leak Test	Pass
6	Water Leak Test	Pass

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable

Approved by

Henry YAN
Laboratory Manager

Yvonne MAO
Senior Analytical Chemical Engineer

CTC SHANGHAI

TEST REPORT

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

Report No.: [redacted] 14 September 2020

APPLICANT: [redacted]

2. Sample(s) description assigned by laboratory:

Size	Analyzed product	Description	Sample information
	GLOVE		
		Whole glove	
		blue vinyl/nitrile palm	

CTC SHANGHAI

TEST REPORT

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

Report No.: [redacted] 14 September 2020

APPLICANT: [redacted]

3. GLOVE/

Whole glove

	Method	Client Requirement	Unit	Result	Conformity
5.2. Dexterity	EN ISO 21420: 2020				
Smallest diameter of pin fulfilling test condition			mm	5.0	
Smallest diameter of pin fulfilling test condition (2)			mm	5.0	
Smallest diameter of pin fulfilling test condition (3)			mm	5.0	
Smallest diameter of pin fulfilling test condition (4)			mm	5.0	
Performance level				5	
• **Air Leak Test**	EN 374-2:2019				Pass
Glove thickness			mm	0.10	
Air pressure used to test			kPa	3.5	
Result		No air bubbles		No air bubbles	
• **Water Leak Test**	EN 374-2:2019				Pass
Result		No water leak		No water leak	

blue vinyl/nitrile palm

	Method	Client Requirement	Unit	Result	Conformity
(+) **4.2. pH - Textile (KCl solution)**	ISO 3071:2020				Pass
pH value		3.5< - <9.5		7.3	
4.2. Aromatic amines derived from azo colorants	ISO 14362-1:2017 (w/o extraction)				Pass
Accessible without fibre extraction		<30	mg/kg	<5	
▲ **4.2. Polycyclic Aromatic Hydrocarbons (8)**	ISO/TS 16190: 2013				Pass
Benzo(a)anthracene		<1	mg/kg	<0.1	
Chrysene		<1	mg/kg	<0.1	
Benzo(b)fluoranthene		<1	mg/kg	<0.1	
Benzo(k)fluoranthene		<1	mg/kg	<0.1	
Benzo(a)pyrene		<1	mg/kg	<0.1	
Dibenzo(a,h)anthracene		<1	mg/kg	<0.1	

CTC SHANGHAI

TEST REPORT

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L4577

Report No.: [illegible] 14 September 2020

APPLICANT: [illegible]

	Method	Client Requirement	Unit	Result	Conformity
Benzo(e)pyrene		<1	mg/kg	<0.1	
Benzo(j)fluoranthene		<1	mg/kg	<0.1	

END OF TEST REPORT

(+)CNAS accreditation

▲: The test was carried out by external accredited laboratory under their accreditation scope.
●: The test was carried out by external accredited laboratory, not within their accreditation scope.

Table of Performance Level for Glove

Test Item	Performance Level					
	0##	1	2	3	4	5
Finger dexterity (EN ISO 21420) Smallest diameter of pin fulfilling test conditions (mm)	—	11.0	9.5	8.0	6.5	5.0

Performance level 0 means the glove falls below the minimum performance level for the given individual hazard

- **Rapport d' essai CTT / Gants de protection synthétiques (GB4806.7)**

CTT

CMA 201819001289 ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L3068

Test Report

Report No.: [redacted] Page 1 of 4

Applicant: [redacted]
Address: [redacted]

Sample Received Date: Aug. 13, 2020
Completed Date: Aug. 31, 2020
Report Date: Aug. 31, 2020

The following merchandise was (were) submitted and identified on behalf of the applicant as:
Sample Name: Disposable Gloves
Model No.: L、S、M、XL

Test Result(s): Please refer to next page(s).

Test Requested and Conclusion(s):

No.	Standard and Requirement	Conclusion(s)
1	GB 4806.7-2016 National food safety standard plastic materials and products for food contact - Overall Migration - Heavy metal (express as Pb) - Potassium permanganate consumption	PASS

Organization: Manny.Li To examine: Tony

Signed for and on Behalf of CTT:

Hilary He

Hilary He
Technical Manager

Consumer Testing Technology Co., Ltd. Click For Authentication

Dongguan Consumer Testing Technology Co., Ltd.
No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: http://www.cttlab.com Email: enquiry@cttlab.com

Test Report

Report No.: [redacted]

Test Result(s):

Overall Migration - GB 4806.7-2016：National Food Safety Standard Food contact plastic articles

Method: GB 31604.8-2016

Material No.	Test Condition	Reporting Limit (mg/dm^2)	Limit (mg/dm^2)	Result (mg/dm^2)	Conclusion
002	4% Acetic acid(v/v) ,70℃ ,2h	3	10	5	PASS

NOTE: 1. mg/dm^2= milligram per square decimeter.
2. N.D. = Not Detected (Less than Reporting Limit).

Test Result(s):

Heavy metal (express as Pb) - GB 4806.7-2016：National Food Safety Standard Food contact plastic articles

Method: GB 31604.9-2016

Material No.	Test Item	Reporting Limit (mg/kg)	Limit (mg/kg)	Result (mg/kg)	Conclusion
001	Heavy metal (express as Pb)	1	1	N.D.	PASS

NOTE: 1. mg/kg = milligram per kilogram (ppm).
2. N.D. = Not Detected (Less than Reporting Limit).
3. Test condition: 4% Acetic acid(v/v), 60℃, 2 hours.

Test Result(s):

Potassium permanganate consumption - GB 4806.7-2016：National Food Safety Standard Food contact plastic articles

Method: GB 31604.2-2016

Material No.	Test Item	Reporting Limit (mg/kg)	Limit (mg/kg)	Result (mg/kg)	Conclusion
001	Potassium permanganate consumption	1	10	N.D.	PASS

NOTE: 1. mg/kg = milligram per kilogram (ppm).
2. N.D. = Not Detected (Less than Reporting Limit).
3. Test condition: distilled water, 60℃, 2 hours.

Dongguan Consumer Testing Technology Co., Ltd.
No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: http://www.cttlab.com Email: enquiry@cttlab.com

Test Report

Report No.: [redacted]

Test Material List

Material No.	Sample Description	Location
001	Blue plastic	Gloves
002	Blue plastic	Gloves

Photo of Sample:

Dongguan Consumer Testing Technology Co., Ltd.
No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: http://www.cttlab.com Email: enquiry@cttlab.com

Test Report

Report No.: [redacted]

End of Report

Dongguan Consumer Testing Technology Co., Ltd.
No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: http://www.cttlab.com Email: enquiry@cttlab.com

CTT CONSUMER TESTING TECH

CMA 201819001289 ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L3068

检测报告

报告编号： [redacted] 第 1 页 共 3 页

申请单位： [redacted]
地　　址： [redacted]

收样日期： 2020 年 08 月 13 日
完成日期： 2020 年 08 月 31 日
报告日期： 2020 年 08 月 31 日

以下检测样品信息是由申请者所提供及确认：
样品名称： 一次性使用手套
样品型号： L、S、M、XL

检测结果： 请参见下页。

检测要求和结论：

序号	标准和要求	结论
1	GB 4806.7-2016 食品安全国家标准 食品接触用塑料材料及制品 - 总迁移量 - 重金属（以铅计） - 高锰酸钾消耗量	合格

东莞市中鼎检验

编制：李敏仪　　审核：

授权签字人：
中鼎检测机构

何晓莹

何晓莹
技术经理

中鼎检测技术有限公司 点击查伪

东莞市中鼎检测技术有限公司
广东省东莞市松山湖高新技术产业开发区工业北四路 7 号
电话：86-0769-8898 9888　传真：86-0769-8898 8808　热线：400 6789 666
网址：http://www.cttlab.com　邮箱：enquiry@cttlab.com

检测报告

报告编号：[redacted]　　第 2 页　共 3 页

检测结果：

总迁移量 - GB 4806.7-2016：食品安全国家标准食品接触用塑料材料及制品

方法：GB 31604.8-2016

材料编号	检测条件	报告限值 (mg/dm²)	限值 (mg/dm²)	结果 (mg/dm²)	单项判定
002	4% 乙酸（v/v），70℃，2h	3	10	5	合格

注释：　1、mg/dm²=毫克每平方分米。
2、N.D. = 未检测到(小于报告限值)。

检测结果：

重金属（以铅计） - GB 4806.7-2016：食品安全国家标准食品接触用塑料材料及制品

方法：GB 31604.9-2016

材料编号	检测项目	报告限值 (mg/kg)	限值 (mg/kg)	结果 (mg/kg)	单项判定
001	重金属（以铅计）	1	1	N.D.	合格

注释：　1、mg/kg = 毫克每千克(ppm)。
2、N.D. = 未检测到(小于报告限值)。
3、测试条件：4% 乙酸(v/v)，60℃，2h。

检测结果：

高锰酸钾消耗量 - GB 4806.7-2016：食品安全国家标准食品接触用塑料材料及制品

方法：GB 31604.2-2016

材料编号	检测项目	报告限值 (mg/kg)	限值 (mg/kg)	结果 (mg/kg)	单项判定
001	高锰酸钾消耗量	1	10	N.D.	合格

注释：　1、mg/kg = 毫克每千克(ppm)。
2、N.D. = 未检测到(小于报告限值)。
3、测试条件：蒸馏水，60℃，2h。

测试材料清单

材料编号	样品描述	位置
001	蓝色塑胶	手套
002	蓝色塑胶	手套

东莞市中鼎检测技术有限公司
广东省东莞市松山湖高新技术产业开发区工业北四路 7 号
电话：86-0769-8898 9888　传真：86-0769-8898 8808　热线：400 6789 666
网址：http://www.cttlab.com　邮箱：enquiry@cttlab.com

检测报告

报告编号：[redacted]　　第 3 页　共 3 页

样品照片：

报告完

东莞市中鼎检测技术有限公司
广东省东莞市松山湖高新技术产业开发区工业北四路 7 号
电话：86-0769-8898 9888　　传真：86-0769-8898 8808　　热线：400 6789 666
网址：http://www.cttlab.com　　邮箱：enquiry@cttlab.com