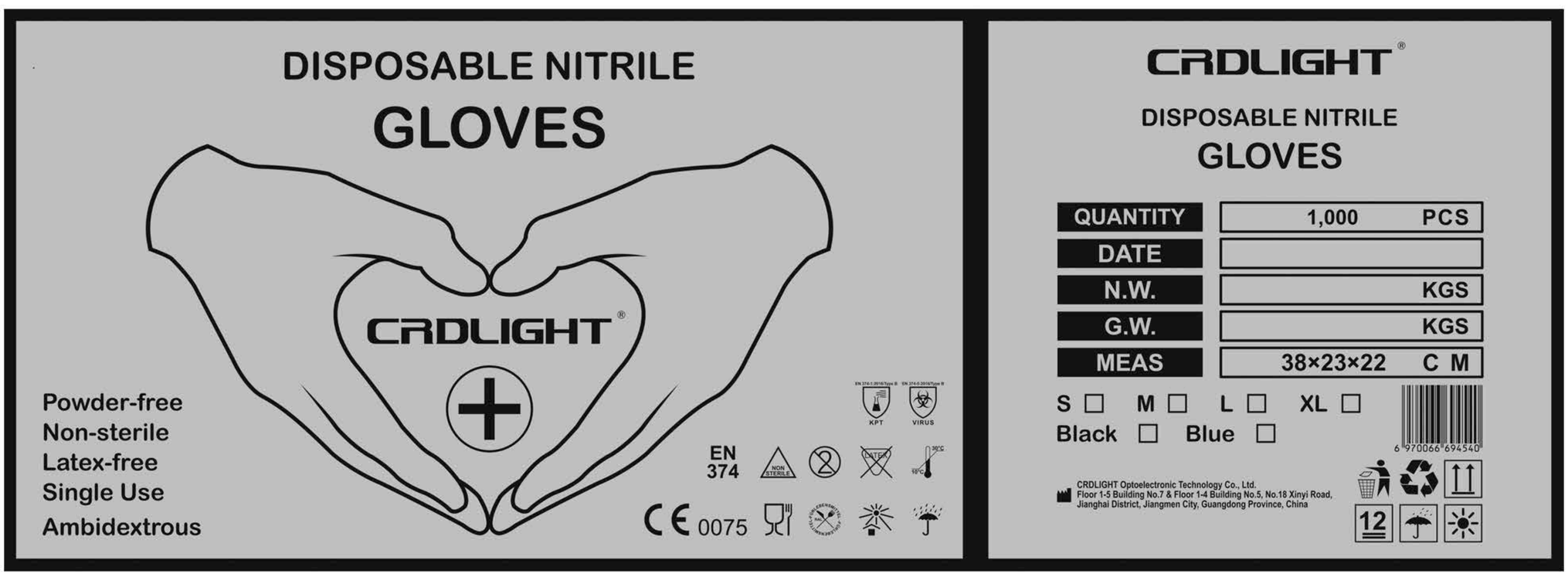
Guantes de nitrilo
con certificación 374-5 y EN455-1-2-3(Caja de 100 unidades)

Características técnicas:

- Cumple con la normativas: 374-5 y EN455-1-2-3
- Peso: 3.5 g - 5g
- Material: Nitrilo
- Color: Azul o negro
- Talla: S, M, L, XL
- Elongación: 500 +
- Caja de 100 unidades
- Fecha de caducidad: 3 años desde su apertura
- No son reutilizables ni lavables



Calle Sierra Filabres 1. Polígono Industrial La Olivilla.
CP:28946. Fuenlabrada (Madrid).

91 632 77 40

tienda@fisaude.com

EC Declaration of Conformity

Manufacturer:

CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO., LTD.
Floor 1-5 Building No.7 & Floor 1-4 Building No.5, No.18
Xinyi Road, Jianghai District, Jiangmen City, Guangdong
Province, China.
Wei Zou
Tel: +86 13929086806
Email: 307027966@qq.com

whose single Authorized EU-Representative:

CMC Medical Devices & Drugs S.L
C/Horacio Lengo N° 18 CP 29006, Málaga-Spain
Tel: +34951214054
Fax: +34952330100

We, the manufacturer, herewith declare that the products:

Disposable Nitrile Examination Gloves

Models: KDNG01M / KDNG02M

meet the provisions of Directive2017/745(EU) which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive2017/745(EU) . It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive2017/745(EU).

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO., LTD.

CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO., LTD.
Floor 1-5 Building No.7 & Floor 1-4 Building No.5, No.18 Xinyi Road, Jianghai District, Jiangmen City, Guangdong Province, China.

Jiang Men China 2021-2-1
Place, date

WEI 2021
Legally binding signature, Function

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/11022021.1

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

CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO., LTD.
Floor 1-5 Building No.7 & Floor 1-4 Building No.5, No.18 Xinyi Road, Jianghai District, Jiangmen City, Guangdong Province, China

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/277/2021**

CE

Issued on: 11/02/2021

Valid until: 10/02/2022

Authorized signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products List

Disposable Nitrile Examination Gloves
Models: KDNG01M / KDNG02M

Disposable Vinyl Examination Gloves
Models: KDPC01M / KDPC02M

Disposable Vinyl/Nitrile Blended Examination Gloves
Models: KDBG01M / KDBG02M

CE

EU-TYPE EXAMINATION CERTIFICATE

The following model of Personal Protective Equipment has been subjected to an EU-type examination in accordance with the module B of the PPE regulation (2016/425) and has been shown to satisfy to essential health and safety requirements.

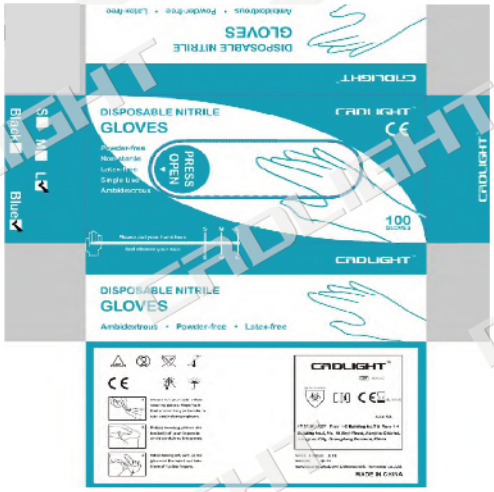
Certificate N° **0075/4279/162/03/21/0537**

Issued by CTC, Notified Body N°0075, to the following model of personal protective equipment :

Manufacturer : **CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD**
1F,2F,3F,4F,5F Floor 1-5 Buliding No.7& Floor 1-4 Buliding No.5,No,18 Xinyi Road,jianghai District,Jiangmen City,Guangdong Province
China

Description

PPE Type : ***protective glove against microorganisms risks***
Product reference : **KDNG01C _BLACK, KDNG02C _BLUE**
Article code : **/**
Glove description : **DISPOSABLE NITRILE GLOVES**
Available sizes : **7/S 8/M 9/L**
Pictures :



Reference standard :	Levels of performance / class of protection
« X » indicates that the glove has not been submitted to the test or the test method appears not to be suitable for the glove design or material. « 0 » indicates that the glove falls below the minimum performance level for the individual hazard.	
EN ISO 21420:2020	-
EN ISO 374-5:2016	**MICRO-ORGANISMS**

This glove is intended to activity that does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent.

At the date of the certificate, the product is in compliance with Annex XVII of REACh regulation (n° 1907/2006 and revisions)

Full description of the PPE, reference rules verified in the context of the EU-type examination and information given on the product are detailed in the manufacturer's technical file and the Instruction for Use index 01 dated from MARCH, 2021

NOTA : Any modification to new items of the personal protective equipment object of this EU type approval certificate or any modification of the information contained in the manufacturer technical file which served for the deliverance of the EU type approval certificate (change of address, change of company status) should be brought to the attention of the notified body in accordance with Annex V §7.2 of Regulation 2016/425. Any marking on the PPE which is not concerned by the Regulation (UE) 2016/425, is not covered by this certificate.

Issued in Lyon by
Didier GUISADO
Certification and Quality Manager

Date of first issue : 19 March 2021
End of validity date : 19 March 2026

CE MARKING CTC NOTIFIED BODY n° 0075 by CTC

In application of the Regulation 2016/425 of the European parliament and the Council of 9th March 2016 related to Personal Protective Equipment and repealing the Directive 89/686/EEC.

cofrac CERTIFICATION DE PRODUITS ET SERVICES
Accreditation n# 5-0594
Scope available on:
www.cofrac.fr

www.ctcgroupe.com
cemarking@ctcgroupe.com
CTC - 4, rue Hermann Frenkel - 69367 Lyon cedex 07 - France
Tél. : +33 (0)4 72 76 10 10 - Fax : +33 (0)4 72 76 10 00 - ctclyon@ctcgroupe.com
Comité Professionnel de Développement Économique (CPDE) Cuir Chaussure Maroquinerie Ganterie
Loi 78-654 du 22.06.1978 - Siret 77564972600160 - Code NAF 9412Z - TVA FR 88775649726

CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD

MANUFACTURER'S TECHNICAL FILE TO THE PPE REGULATION 2016/425

Reference of the product	:	KDNG01C _BLACK, KDNG02C _BLUE
Article code	:	/
Technical file index	:	01
Last update	:	MARCH, 2021

IDENTIFICATION

Reference of the product :	:	KDNG01C _BLACK, KDNG02C _BLUE
Article code :	:	/
Basic Model		
Technical file index :	:	01
Last update :	:	MARCH, 2021

Manufacturer :

CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD

1F,2F,3F,4F,5F Floor 1-5 Buliding No.7& Floor 1-4 Buliding No.5,No,18 Xinyi Road,jianghai District,Jiangmen City,Guangdong Province

China

tel : 07503766087

fax : 07503808345

Factory :

CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD

1F,2F,3F,4F,5F Floor 1-5 Buliding No.7& Floor 1-4 Buliding No.5,No,18 Xinyi Road,jianghai District,Jiangmen City,Guangdong Province

China

tel: 07503766087

fax: 07503808345

GLOVE DESCRIPTION

General glove description and intended use:

DISPOSABLE NITRILE GLOVES

This glove is designed against microorganisms risks .

This glove is intended to activity that does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent.

Type of coating finish : no coating

Visual description (picture back and palm sides) :

Risk assessment (Essential Health and Safety Requirement. Annex II - PPE Regulation)			
		Applicable	Covered by
§1	Requirements defined in the Annex II §1 are applicable to all PPE	☑	☑ Standard ☑ Instruction for use ☑ Marking
§1.4	Manufacturer's instructions and information is available	☑	☐ Standard ☑ Instruction for use ☐ Marking
§2.4	If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.	☑	☑ Standard ☑ Instruction for use ☑ Marking
§2.5	PPE which may be caught up during use	☑	☐ Standard ☑ Instruction for use ☐ Marking
§2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	☑	☑ Standard ☑ Instruction for use ☑ Marking
§3.10.2	PPE intended to protect against substances and mixtures which are hazardous to health and against harmful biological agents - Cutaneous contact	☑	☑ Standard ☑ Instruction for use ☑ Marking

Glove constitution :

	Reference	Color	Material	Surfacic mass	Gauges	Thickness
Palm		black or blue	Nitrile			0.115MM
Back		black or blue	Nitrile			0.115MM
Cuff		black or blue	Nitrile			0.115MM

PROTECTION SCOPE

This glove meets the essential requirements of the Personal Protective Equipment Regulation 2016/425.

This glove is designed against microorganisms risks .

It is a category II product.

GENERAL REQUIREMENTS

Standard EN ISO 21420 : 2020

Dexterity : 5

Available size range: 7/S-9/L

A different hand sizing system from the one defined in EN ISO 21420 Annex B table B.1 is used:

Hand size	Hand circumference (mm)	Hand length (mm)
7/S	170	161
8/M	190	168
9/L	210	175

SPECIFIC REQUIREMENTS AND PERFORMANCE LEVELS

« X » indicates that the glove has not been submitted to the test or the test method appears not to be suitable for the glove design or material.

« 0 » indicates that the glove falls below the minimum performance level for the individual hazard.

Microorganism EN ISO 374-5 : 2016

This glove protect against microorganism.
The glove shall be used in following conditions :
Work place or similar :
- Work in food production plants
- Work in agriculture.
- Work activities where there is contact with animals and/or products of animal origin.
- Work in healthcare, including isolation and post-mortem units.
- Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.
- Work in refuse disposal plants
- Work in sewage purification installations

The activity does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent
Uncontrolled against viruses.

TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	S210100570_1	
EN ISO 374-5	S210100570_1	

MARKING - PACKAGING

Information printed on the box :

Logo of Manufacturer :
Logo CE
Glove's reference : KDNG01C _BLACK, KDNG02C _BLUE
Article Code : /
Size indicator
Pictograms related to risks against which protection is offered with performance levels
Information pictogram
Address of Manufacturer :
Date of Manufacture (month/year) and/or serial/batch number :
Date of obsolescence (month/year) if applicable:

Marking of packaging example :

Method of marking on the glove :

Print on the box

Packaging suitable for transport:

100 pcs per box, 1000 pcs per carton

PPE subject to ageing :

Peremption period : 3 years when stored in appropriate conditions (humidity, temperature, clean , ventilated, light). Before use, the glove shall be visually controlled, in case of deterioration the gloves must be scrapped (abrasion, cut, tear, …).

Cleaning instructions:

The gloves are not washable.

MEANS OF CONTROL

1. According to certain chemical standard, we test and check the raw material before we accept them from our supplier, we keep the material at proper place and condition, marked available date and code of supplier.
2. Mainly we check the raw material for every batch. We put them at the certain place in warehouse.
3. For coating, packing precessing, every step check the last step, signing the name of the last one.
4. We do a simple and tested by a competent laboratory CTC Shanghai as per Air leak & Water leak testing every one month. If the test result compliance with the relevant standards and reach to our requirement, we will produce mass production same as the samples, and check at least 2% of total quantity before shipment.

INSTRUCTION FOR USE

CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD

1F,2F,3F,4F,5F Floor 1-5 Buliding No.7& Floor 1-4 Buliding No.5,No,18 Xinyi Road,jianghai District,Jiangmen City,Guangdong Province

China

Glove reference : KDNG01C _BLACK, KDNG02C _BLUE

Article code: /

User notice index : 01

Last update : MARCH, 2021

Glove description :

DISPOSABLE NITRILE GLOVES

This glove is a personal protective equipment belonging to the category II.

It meets the requirements of the PPE Regulation 2016/425 : innocuousness, comfort, solidity.

It has been subject to a UE-type Examination performed by :

C.T.C. (0075)

4, rue Hermann Frenkel

69367 LYON Cedex 07

FRANCE

Applicable standards :

The glove meets the requirements of the standard EN ISO 21420:2020 « Protective Gloves - General requirements and test methods ».

Dexterity: 5

Available size range: 7/S-9/L

A different hand sizing system from the one defined in EN ISO 21420 Annex B is used:

Hand size	Hand circumference (mm)	Hand length (mm)
7/S	170	161
8/M	190	168
9/L	210	175

Moreover, this glove has been designed for the following applications :

« X »indicates that the glove has not been submitted to the test or the test method appears not to be suitable for the glove design or material.

« 0 » indicates that the glove falls below the minimum performance level for the individual hazard.

Application :

Microorganism - EN ISO 374-5 : 2016

Microorganism resistant	Conform

Read carefully the instructions for use provided with the product

Protection limit :

Users should be warned that gloves should not be worn when there is a risk of entanglement by moving parts of machines.

This model does not contain any substances at levels that are known to, or suspected to, adversely affect user hygiene or health.

The protection against risks or hazards which are not mentioned in this document is not warranted.

These levels of performance are obtained from the tests done according to conditions defined by the applicable standards.

The levels of performance mentioned are only valid for new gloves, not washed, nor regenerated.

Before use, the glove shall be visually inspected for any defect or imperfections. In case of deterioration, the gloves must be scrapped (abrasion, cut,

No flame protection is claimed. This glove shall not be in contact with naked flame.

The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

The glove shall be used in following conditions :

Work place or similar :
- *Work in food production plants*
- *Work in agriculture.*
- *Work activities where there is contact with animals and/or products of animal origin.*
- *Work in healthcare, including isolation and post-mortem units.*
- *Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.*
- *Work in refuse disposal plants*
- *Work in sewage purification installations*

The activity does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent.

Uncontrolled against viruses.

Storage and cleaning notice

Keep in its original packaging, under ordinary temperature and humidity conditions and in clean, covered and ventilated premises.

The gloves are not washable.

PPE subject to ageing :

Peremption period : 3 years when stored in appropriate conditions (humidity, temperature, clean , ventilated, light). Before use, the glove shall be visually controlled, in case of deterioration the gloves must be scrapped (abrasion, cut, tear, ...).

Declaration of conformity :

Available with product.

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

Report No.: S210301983_1

22 April 2021

APPLICANT: CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD江门市卡迪光电科技有限公司 (C41964)

FLOOR 1-5 BULIDING NO.7&FLOOR 1-4 BULIDING NO.5,NO,18 XINYI ROAD, JIANGHAI DISTRICT JIANGMEN GUANGDONG CHINA

307027966@qq.com

Date of receipt :18 Mar. 2021
Testing period :22 Apr. 2021
:22 Apr. 2021

Buyer: —

Sample description: size:X,M,L,XL

Style / Article no. :蓝色KDNG02C
Test(s) requested :—
Service :REGULAR
Brand / Section :—
Season :—
End use :一次性丁腈手套 Disposable Nitrile 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
1	Resistance to penetration by blood-borne pathogens - Test method using Phi-X174 bacteriophage	**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

TEST REPORT

Report No.: S210301983_1

22 April 2021

APPLICANT: CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD江门市卡迪光电科技有限公司 (C41964)

2. Sample(s) description assigned by laboratory:

Size	Analyzed product	Description	Sample information
	GLOVE	blue nitrile glove	

210301983

APPLICANT: CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD江门市卡迪光电科技有限公司 (C41964)

3. GLOVE/

blue nitrile glove

	Method	Client Requirement	Unit	Result	Conformity
▲ **Resistance to penetration by blood-borne pathogens - Test method using Phi-X174 bacteriophage**	ISO/FDIS 374-5:2016				Pass
Type of sample				Glove	
Dimension of the test specimens				7.5cm x 7.5cm	
Sampling				Palm	
Paraffin-sealed edges				No	
Test specimens condition				21±5°C and 60±10%RH	
Sterilization				None	
Pre treatment performed				None	
Side in contact with the bacteriophage suspension				Outer side	
Test procedure used				Procedure B (0kPa 5min + 14kPa 1min + 0kPa 4min - With screen)	
Retaining screen specifications					
Surface tension of the bacteriophage suspension				0.042 ± 0.002N/m	
Used bacteriophage				Bacteriophage Phi-X174 (ATCC13706-B1)	
Host bacteria				Escherichia coli (ATCC 13706)	
Compatibility ratio				1.1	
Starting bacteriophage challenge titer			PFU/ml	2.46 10^8	
Starting bacteriophage challenge titer (2)			PFU/ml	2.46 10^8	
Starting bacteriophage challenge titer (3)			PFU/ml	2.46 10^8	
Ending bacteriophage challenge titer			PFU/ml	2.37 10^8	
Ending bacteriophage challenge titer (2)			PFU/ml	2.40 10^8	
Ending bacteriophage challenge titer (3)			PFU/ml	2.49 10^8	
Environmental plate results				0 PFU on each settle plate	
Number of PFU/ml of assay fluid		<1 (No penetration)		<1 (No penetration)	
Number of PFU/ml of assay fluid (2)		<1 (No penetration)		<1 (No penetration)	

TEST REPORT

Report No.: S210301983_1

22 April 2021

APPLICANT: CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD江门市卡迪光电科技有限公司 (C41964)

	Method	Client Requirement	Unit	Result	Conformity
Number of PFU/ml of assay fluid (3)		<1 (No penetration)		<1 (No penetration)	

END OF TEST REPORT

▲: The test was carried out by external accredited laboratory under their accreditation scope.

scan to see the report

QDHL2101000813MD

检 测 报 告

Test Report

报告编号 Report No.: QDHL2101000813MD

样 品 名 称：	一次性医用丁腈检查手套
Sample Description:	DISPOSABLE NITRILE EXAMINATION GLOVE
委 托 单 位：	江门市卡迪光电科技有限公司
Applicant:	CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD
检 测 类 别：	委托检测
Test Type:	SUBMITTED BY CLIENT

通标标准技术服务(青岛)有限公司

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

中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com

报告编号 Report No.: QDHL2101000813MD

检 测 报 告

Test Report

样品信息 Sample information	样品名称 Sample Description	一次性医用丁腈检查手套 DISPOSABLE NITRILE EXAMINATION GLOVE	颜色 Color	蓝色 BLUE
	收到样品数量 Received sample quantity/ 测试样品数量 Tested sample quantity	S/M/L: 500 只 500PCS/ S/M/L: 230 只 230PCS	型号/规格 Type/ Specifications	KDNG02M
	产品批号 Lot No.	未提供 NOT PROVIDED	生产批量 Lot Quantity	未提供 NOT PROVIDED
	生产日期 Manufacture Date	未提供 NOT PROVIDED	有效期 Expiration Date	3 年 THREE YEARS
	材质/外观形态 Material/ Appearance	丁腈 NITRILE	保存条件 Storage Condition	未提供 NOT PROVIDED
	生产厂家 Manufacturer	未提供 NOT PROVIDED		
客户信息 Client information	委托单位 Applicant	江门市卡迪光电科技有限公司 CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD		
	委托单位地址 Applicant address	江门市江海区信义路 18 号 5 幢 1F,2F,3F,4F,7 幢 1F,2F,3F,4F,5F FLOOR 1-5 BULIDING NO.7& FLOOR 1-4 BULIDING NO.5,NO,18 XINYI ROAD,JIANGHAI DISTRICT,JIANGMEN CITY,GUANGDONG PROVINCE,CHINA		

报告编号 Report No.: QDHL2101000813MD

检测信息 Test information	样品接收日期 Sample Receiving Date	2021 年 01 月 25 日 JAN.25,2021	样品检测周期 Test Period Date	2021 年 01 月 25 日至 2021 年 02 月 08 日 JAN.25,2021 TO FEB.08,2021
	样品编号 Sample No.	QDHL2101000813MD (TAOHG2100385701) (TAOHG2100385702)	检测环境 Test environment	符合要求 Meet requirement
	检测项目 Test items	不透水试验，尺寸（长度，宽度），拉伸强度（老化前扯断力，老化后扯断力），可沥滤蛋白质 Water tightness test, Dimensions(Length, Width), Tensile strength (Force at break, Force at break after challenge testing), Proteins, leachable		
	检测依据 Testing Accordance	EN 455-1:2020 一次性使用医用手套–第 1 部分:不透水试验 条款 5.1 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 一次性使用医用手套–第 2 部分:物理性能要求和试验条款 4.2,4.3,5.2,5.3 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 EN 455-3:2015 一次性使用医用手套–第 3 部分:生物学评价要求和试验条款 4.5 EN 455-3:2015 Medical Gloves for Single Use–Part 3: Requirements and Testing for Biological Evaluation clause 4.5		

报告编号 Report No.: QDHL2101000813MD

检测结论 Test conclusion	本报告仅提供实测数据和单项判定，详见检测结果汇总页。 This report only provides the test results and individual judgment, conclusion please see follow pages. 签发日期：2021 年 02 月 08 日 Issue date: FEB.08,2021
备注 Remark	/

批准人：　　审核人：　　编制人：

日期：2021 年 02 月 08 日　　日期：2021 年 02 月 08 日　　日期：2021 年 02 月 08 日

样品照片
Sample Photo

中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com

检 测 结 果
Test Results

检测项目 Test Items		单位 Unit	检测方法 Test Method	标准要求 Requirement	检测结果 Test Result	单项判定 Assessment
不透水试验 Water tightness test		/	EN 455-1: 2020 条款 5.1 EN 455-1: 2020 Clause 5.1	样品数量：S:200 只 M:200 只 L: 200 只 Sample quantity: S:200pcs M: 200pcs L: 200pcs 接收质量限 AQL: 1.5 接收数 Ac: 7 拒收数 Re: 8	不符合样品数 Found: S: 0 M: 0 L: 1	符合 Pass
尺寸 Dimensions	长度 Length	mm	EN 455-2:2015 条款 4.2 EN 455-2:2015 Clause 4.2	中值 Median value: ≥240	详见附录一 See appendix 1 for details	符合 Pass
	宽度 Width	mm	EN 455-2:2015 条款 4.3 EN 455-2:2015 Clause 4.3	中值 Median value: S: 80±10 M: 95±10 L: 110±10		符合 Pass
拉伸强度 Tensile Strength	老化前扯断力 Force at break	N	EN 455-2:2015 条款 5.2 EN 455-2:2015 Clause 5.2	中值 Median value: b): ≥6.0	详见附录二 See appendix 2 for details	符合 Pass
	老化后扯断力 Force at break after challenge testing	N	EN 455-2:2015 条款 5.3 EN 455-2:2015 Clause 5.3	中值 Median value: b): ≥6.0		符合 Pass

检测项目 Test Items	单位 Unit	检测方法 Test Method	标准要求 Requirement	检测结果 Test Result	单项判定 Assessment
可沥滤蛋白质 Proteins, leachable	μg/g	EN 455-3: 2015 条款 4.5 EN 455-3: 2015 clause 4.5	/	S: 未检出 Not Detected M: 未检出 Not Detected L: 未检出 Not Detected （检出限：10） (Method Detection Limit: 10)	/

附录一：尺寸
Appendix 1: Dimensions

样品尺码 Size	S	
样品编号 No.	长度 Length (mm)	宽度 Width (mm)
1	250	86
2	249	86
3	249	86
4	254	86
5	249	86
6	252	86
7	245	86
8	250	86
9	248	86
10	250	86
11	255	86
12	248	86
13	250	86
标准要求 Standard requirement	≥240	80±10
中值 Median value	250	86

报告编号 Report No.: QDHL2101000813MD

样品尺码 Size	M	
样品编号 No.	长度 Length (mm)	宽度 Width (mm)
1	245	98
2	245	98
3	248	97
4	245	97
5	250	98
6	249	97
7	250	98
8	248	98
9	245	98
10	248	98
11	247	98
12	248	98
13	248	97
标准要求 Standard requirement	≥240	95±10
中值 Median value	248	98

报告编号 Report No.: QDHL2101000813MD

样品尺码 Size	L	
样品编号 No.	长度 Length (mm)	宽度 Width (mm)
1	260	110
2	255	110
3	265	110
4	260	109
5	258	110
6	258	109
7	260	110
8	265	109
9	260	110
10	255	110
11	260	110
12	260	109
13	256	110
标准要求 Standard requirement	≥240	110±10
中值 Median value	260	110

附录二：拉伸强度
Appendix 2: Tensile Strength

尺码 Size: S			
扯断力 Force at break (N)			
老化前 Before aging		老化后 After aging	
样品编号 No.	/	样品编号 No.	/
1	8.4	1	7.6
2	8.1	2	8.7
3	6.8	3	7.0
4	6.9	4	7.1
5	6.1	5	7.5
6	6.8	6	6.1
7	8.4	7	6.6
8	8.2	8	8.0
9	9.0	9	7.6
10	8.1	10	8.1
11	8.3	11	7.9
12	6.5	12	7.0
13	7.7	13	6.8
标准要求 Standard requirement	≥6.0	标准要求 Standard requirement	≥6.0
中值 Median value	8.1	中值 Median value	7.5

中国·山东·青岛市崂山区株洲路143号通标中心 邮编：266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com

报告编号 Report No.: QDHL2101000813MD

尺码 Size: M			
扯断力 Force at break (N)			
老化前 Before aging		老化后 After aging	
样品编号 No.	/	样品编号 No.	/
1	4.1	1	6.3
2	6.0	2	6.7
3	6.8	3	7.7
4	6.5	4	7.4
5	7.7	5	6.9
6	5.5	6	6.7
7	5.8	7	7.6
8	7.2	8	7.9
9	8.1	9	7.1
10	7.3	10	6.7
11	7.8	11	8.0
12	5.4	12	6.9
13	7.0	13	7.1
标准要求 Standard requirement	≥6.0	标准要求 Standard requirement	≥6.0
中值 Median value	6.8	中值 Median value	7.1

报告编号 Report No.: QDHL2101000813MD

尺码 Size: L			
扯断力 Force at break (N)			
老化前 Before aging		老化后 After aging	
样品编号 No.	/	样品编号 No.	/
1	6.7	1	6.0
2	8.0	2	9.2
3	7.6	3	8.3
4	6.0	4	6.8
5	8.1	5	6.5
6	6.0	6	8.3
7	7.6	7	7.7
8	7.2	8	7.6
9	7.6	9	7.7
10	6.2	10	8.0
11	7.6	11	8.6
12	6.6	12	7.1
13	6.2	13	7.6
标准要求 Standard requirement	≥6.0	标准要求 Standard requirement	≥6.0
中值 Median value	7.2	中值 Median value	7.7

Remark:

符合性声明仅基于本次实验室活动的实测值，未将本次实验室活动的测量不确定度影响计入。
The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

结束
End of Report

注意事项
Statement

1. 报告无批准人签字、“检验检测专用章”或经涂改，以及复印报告未加盖“检验检测专用章”均视作无效。
   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. 样品及相关信息由客户提供及确认，SGS 不承担证实客户提供信息的准确性、适当性和(或)完整性责任。
   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. 除非另有声明，本测试报告所示结果仅涉及受测试样品。检测报告仅用于客户科研、教学、内部质量控制、产品研发等目的，仅供内部参考。
   Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. The test report shall only be used for clients' scientific research, teaching, internal quality control, product research and development, etc… and just for internal reference.

4. 未经本公司批准，不得复制(全文复制除外)报告或证书。
   The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.

5. 对检测报告若有异议，应于收到报告之日起十五日内向本单位提出。
   Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

地　址：青岛市崂山区株洲路 143 号
Address: SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

电话：0532-68999187　　邮编：266101　　传真：0532-80991952
Tel: 0532-68999187　　Zip: 266101　　Fax: 0532-80991952

E-mail：Emily.Zhang@sgs.com