

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° 0075/4279/162/09/21/1586

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 Building No.7& Floor 1-4 Building

China

Description

PPE Type: protective glove against chemical risks, microorganisms risks

Product reference: KDNG02M

Glove description: Disposable Nitrile Gloves

Available sizes: 7/S 8/M 9/L 10/XL

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 AND VIRUS

EN ISO 374-1:2016 / A1:2018

Type C

This product is a category III (letal or irreversible risk). This certificate shall only be used in conjuncture with the conformity assessment procedure according to module C2 (CTC 0075)

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 September 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: 20 September 2021 End of validity date: 20 September 2026



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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.



CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD

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

Reference of the product : KDNG02M

Article code :

Technical file index : 01

Last update : September 2021

IDENTIFICATION

Reference of the product: : KDNG02M

Article code:

Basic Model

Technical file index: 01

Last update : September 2021

Manufacturer:

CRDLIGHT OPTOELECTRONIC TECHNOLOGY CO.,LTD

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China

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Factory:

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China

tel: 07503766087 fax: 07503808345

GLOVE DESCRIPTION

General glove description and intended use:

Disposable Nitrile Gloves

This glove is designed against chemical risks, microorganisms risks.

Type of coating finish: no coating

Visual description (picture back and palm sides):



	Risk assessment (Essential Health and Safety Requirement. Annex II -	PPE Regula	ation)
		Applicable	Covered by
§1	Requirements defined in the Annex II §1 are applicable to all PPE	√	✓ Standard✓ Instruction for us✓ Marking
§1.4	Manufacturer's instructions and information is available	\ \	Standard ✓ Instruction for us 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 us Marking
§2.5	PPE which may be caught up during use		Standard Instruction for us Marking
§2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety		✓ Standard ✓ Instruction for us ✓ Marking
§2.14	Multi-risk PPE	✓.	✓ Standard✓ Instruction for us✓ 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 us ✓ Marking

Glove constitution:

	Reference	Color	Material	Surfacic mass (g/m²)	Gauges	Thickness
Palm		Blue	Nitrile			0.09MM
Back		Blue	Nitrile			0.09MM
Cuff		Blue	Nitrile			0.09MM

PROTECTION SCOPE

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

This glove is designed against chemical risks, microorganisms risks.

It is a category III product, module C2

Notified Body Reference: CTC (0075)

Parc Scientifique Tony Garnier, 4, rue Hermann Frenkel-

69367 Lyon Cedex 07-France

GENERAL REQUIREMENTS

Standard EN ISO 21420 : 2020

Dexterity: 5

Available size

7/S-10/XL

range:

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
10/XL	230	183

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.

Chemical hazard EN 374-2: 2014

Protection offered	Performance levels	
Water tightness	conform	
Air tightness	conform	

Chemical hazard EN ISO 374-1: 2016 / A1: 2018

	Type:	Type C		
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Tested chemical :	CAS N°	Letter	Permeation performance levels:	Degradation value:
Sodium hydroxide 40%	1310-73-2	K	6	2,1%
Hydrogen peroxide 30%	7722-84-1	Р	2	31,4%
Formaldehyde 37%	50-00-0	Т	1	13,0%

Microorganism EN ISO 374-5: 2016

This glove protect against microorganism.
Controlled against viruses.

TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	S210403678_2	
EN 374-2	S210403678_2	
EN 16523-1	S210403678_2	
EN ISO 374-5	S210301983_4	
Other	S210301984_3(EN374-4)	

MARKING - PACKAGING

Information printed on the glove:

Logo of Manufacturer:

Logo (€

Glove's reference: KDNG02M

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 example:



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 sample 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.